EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 3-26

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-14-001	11/01/2013 To 10/31/2017 Base Option Period Number 3	BOSC Meeting

Contractor: ICF INCORPORATED, L.L.C.

Specify Section and paragraph of Contract SOW: E 1 & 2

Purpose:
- ☒ Work Assignment
- ☐ Work Assignment Amendment
- ☐ Work Plan Approval
- ☐ Work Assignment Close-Out
- ☐ Incremental Funding

Period of Performance: From 11/01/2016 To 10/31/2017

Comments:

☐ Superfund — Accounting and Appropriations Data — ☒ Non-Superfund

SFO (*Max 2*): ☐

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

	Cost/Fee	LOE
Contract Period: 11/01/2013 To 10/31/2017		
This Action:		
Total:		

Work Plan / Cost Estimate Approvals

	Cost/Fee	LOE
Contractor WP Dated:		
Cumulative Approved:		

Work Assignment Manager Name: Tom Tracy (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	202-564-6518
	FAX Number:	
Project Officer Name: Melissa Revely-Wilson (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	919-541-0207
	FAX Number:	
Other Agency Official Name (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	
	FAX Number:	
Contracting Official Name: William Yates (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	513-487-2055
	FAX Number:	

PERFORMANCE WORK STATEMENT
CONTRACT NO. EP-C-14-001
WA 3-26

TITLE: Board of Scientific Counselors (BOSC) Meeting / Conference Support

Specify Section & Paragraph SOW: E. Risk Assessment Support

1. Science Writing, Risk Communication and Training
2. Administration and Technical Support for NCEA Human Health Related Meetings

PERIOD OF PERFORMANCE: November 1, 2016 thru October 31, 2017

1. BACKGROUND

The primary functions of the BOSC include evaluating ORD's science and engineering research programs, laboratories, and research-management practices, and recommending actions to improve their quality and/or strengthen their relevance to the mission of the EPA. For more information on the BOSC, go to http://epa.gov/osp/bosc/.

2. PURPOSE

The purpose of this Work Assignment is to provide: a full range of administrative and logistical support services for the conduct of Federal Advisory Committee meetings, conferences and/or teleconferences related to the Charter of the Office of Research and Development's Board of Scientific Counselors (BOSC); administrative activities required for reports prepared by the BOSC Executive Committee or it's Subcommittees; and the full range of administrative support services for assimilating materials collected from extensive candidate searches conducted for either the Executive Committee, or existing or proposed Subcommittees.

The contractor's activities will not require special expertise in matters of science discussed by the Board, but the contractor should possess the practical knowledge, experience, and skills commonly used in facilitating high-level policy meetings.

Meetings of the BOSC Executive Committee and Subcommittees will generally be held on-site at US EPA (either Headquarters or a Laboratory/Center, as appropriate), if space is available, with the approval of the Designated Federal Officer (DFO). Under this work assignment, it is anticipated that contractor support shall be required for approximately four Executive Committee meetings (at least 1 is expected to be face-to-face meetings); approximately 5 face-to-face program review subcommittee meetings. In addition, contractor support shall be needed for approximately 17 conference calls (expected to be 2-3 hour calls) in support of the executive committee and subcommittee meetings. The EPA WAM will provide the meeting dates via written technical direction.

It is anticipated that approximately 6 reports shall be generated by the BOSC during the timeframe of this work assignment, and that candidate searches requiring contractor support may occur no more than 2 times per year.

3. STATEMENT OF WORK

This Statement of Work describes EPA's requirements regarding services to be rendered by the contractor for BOSC meeting and conference support. The contractor shall provide the necessary personnel and resources in the following four areas for the BOSC:

1. Pre-meeting communication and logistical support.
2. On-site technical support during meetings/teleconferences.
3. Prepare summary minutes of meetings/teleconferences.
4. Word processing for reports.

Task 1. Pre-meeting communication and logistical support

As requested by the EPA WAM, the contractor shall prepare a BOSC member's background binder for the list of invitees provided by the EPA WAM, to include agenda, minutes of last meeting (if appropriate), other background/logistical material needed for the meeting/teleconference. Via written technical direction, the meeting/teleconference dates will be provided by the EPA WAM. The contractor shall prepare a mail merge file and address labels for the list of members and invitees. All correspondence shall be transmitted under the Designated Federal Officer's name. It is anticipated that there will be approximately 30 participants for each Executive Committee meeting, and approximately 20-100 participants for each Subcommittee face-to-face meeting.

The contractor shall obtain meeting space facilities when government owned facilities are not available, as determined by the EPA WAM (this includes negotiation with hotels or other entities to obtain meeting space, as well as reservations (room blocks) for lodging that fall within U.S. Government per-diem rates and meet Agency lodging requirements).

Task 2. On-site technical support during meetings/teleconferences

The contractor shall provide recorders to take minutes at each meeting/teleconference. The contractor shall ensure that all equipment needed at the meeting is available, to include microphone equipment, laptop computers, etc., as needed and specified by the EPA WAM.

The contractor shall provide a registration table each day of the meeting and shall provide table tents and name badges of participants. The contractor shall also photocopy additional sets of handouts and materials as may be required during the course of the meeting, on a fast turnaround basis, as requested by the EPA WAM.

The contractor shall deliver to the EPA WAM any materials not distributed at the meeting or materials left behind by BOSC members within two working days after the meeting.

Task 3. Prepare summary minutes of meetings/teleconferences

The contractor shall prepare and submit to the EPA WAM draft minutes of the

meetings/teleconferences within 15 working days of the end of each meeting/teleconference. The contractor shall incorporate comments and changes to the minutes per written technical direction by the EPA WAM and submit final minutes within 5 working days of receiving EPA comments. The draft and final minutes shall be provided in electronic format (Word is the Agency standard software).

Task 4. Word Processing for Reports

The contractor shall provide word processing support for any reports prepared by the BOSC Executive Committee or its Subcommittees. The contractor shall not be involved in developing the technical content of the report, and shall not provide any scientific technical expertise. The contractor shall only provide word processing services to compile, format, edit (based on Executive Committee and Subcommittee member input, plus any factual changes requested by ORD and approved by the Executive Committee), and finalize reports prepared by the Executive Committee or its Subcommittees.

The contractor shall compile/format/edit and submit draft Executive Committee/ Subcommittee reports to the EPA WAM within 15 working days after receiving report content. The contractor shall incorporate comments and changes to the reports and submit final reports to the EPA WAM within 5 working days of receiving comments. The draft and final reports shall be provided in electronic format (Word is the Agency standard software).

5. SCHEDULE OF DELIVERABLES

Product	Due Date
Logistical Arrangements of Meeting	60 working days prior to meeting
Draft Minutes of Meeting (To EPA WAM)	15 working days after completion of meeting
Final Minutes of Meeting (to EPA WAM)	5 working days after receipt of comments from EPA WAM
Draft Exec Committee/Sub-committee reports (to	15 working days after receipt of report EPA WAM) content from EPA WAM
Final Exec Committee/Sub-committee reports (to	5 working days after receipt of comments EPA WAM) from EPA WAM

6. SPECIAL CONDITIONS

Final products shall be produced by the Contractor upon EPA WAM's approval through written technical direction. The Contractor shall provide all materials written under these tasks to the EPA WAM, as per work assignment, in electronic form. Electronic version shall be compatible with the ORD's computer systems and software, (e.g., Microsoft Word).

Separate from the Monthly Progress Report, the contractor costs shall be provided to the EPA WAM on a monthly basis, and shall be compiled separately for the Executive Committee and each Subcommittee. EPA is required to annually input cost information for each committee or subcommittee into a government-wide database, and EPA will not be able to comply with this federal requirement unless contractor costs are tracked and reported to EPA by each committee/subcommittee.

7. CONFIDENTIALITY

Some of the work assigned under these tasks may be to draft, edit, and review program and sensitive organizational information that will not be ready for broad or public distribution. The contractor shall not discuss the contents of any document with anyone not specified as a participant in the documents review process or its preparation. The EPA WAM will supply the contractor with a list of individuals involved with any documents under these tasks.

8. MANAGEMENT CONTROLS

Periodic meetings between the EPA and contractor work assignment managers are encouraged to discuss any questions that may arise during performance or completion of this work assignment. At the EPA WAM's discretion, these meetings may occur via teleconference or video conferences. The contractor shall document these meetings and submit copies of this correspondence to the EPA WAM.

The EPA WAM may identify one or more EPA technical representatives for this work assignment. Interaction between the contractor and any EPA technical representative(s) designated by the EPA WAM is solely for the purpose of presenting and discussing the information, analyses, results, or presentations related to this work assignment. The interaction will be technical communication vice technical direction. Per the technical direction clause EPAAR 1552.237-71 of the contract, the PO and the WAM or alternate WAM are the primary representatives of the CO authorized to provide technical direction.

WORK ASSIGNMENT CONTRACT OFFICER REPRESENTATIVE (WA-COR) AND ALTERNATE WA-COR

WA-COR:

Thomas Tracy
Designated Federal Officer
Board of Scientific Counselors
Office of Research and Development
U.S. Environmental Protection Agency
Mail Code 8104R
1200 Pennsylvania Avenue, NW
Washington, DC 20460

202-564-6518

Alternate WA-COR:

Anthony Grimm

Office of Science Policy
Office of Research and Development
U.S. Environmental Protection Agency
Mail Code 8104R
1200 Pennsylvania Avenue, NW
Washington, DC 20460

202-564-0153

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 3-31

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-14-001	11/01/2013 To 10/31/2017 Base Option Period Number 3	Epidemiologic Support for IRIS

Contractor: ICF INCORPORATED, L.L.C.

Specify Section and paragraph of Contract SOW: A.1,2; B.1,2,3,4,5; C.1; D; and G.1,2

Purpose:
- [X] Work Assignment
- [ ] Work Assignment Amendment
- [ ] Work Plan Approval
- [ ] Work Assignment Close-Out
- [ ] Incremental Funding

Period of Performance: From 11/01/2016 To 10/31/2017

Comments:

☐ Superfund — Accounting and Appropriations Data — [X] Non-Superfund

SFO (*Max 2*): ☐

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

Contract Period: 11/01/2013 To 10/31/2017 — Cost/Fee: — LOE:

This Action:

Total:

Work Plan / Cost Estimate Approvals

Contractor WP Dated: — Cost/Fee — LOE:

Cumulative Approved: — Cost/Fee — LOE:

Work Assignment Manager Name: Amanda Persad (Signature) (Date)	Branch/Mail Code: Phone Number: 919-541-9781 FAX Number:
Project Officer Name: Melissa Revely-Wilson (Signature) (Date)	Branch/Mail Code: Phone Number: 919-541-0207 FAX Number:
Other Agency Official Name: (Signature) (Date)	Branch/Mail Code: Phone Number: FAX Number:
Contracting Official Name: William Yates (Signature) (Date)	Branch/Mail Code: Phone Number: 513-487-2055 FAX Number:

PERFORMANCE WORK STATEMENT
CONTRACT NO. EP-C-14-001
WA 3-31

TITLE: Epidemiologic Support for IRIS

Principal Section & Paragraph of SOW: A.1,2; B.1,2,3,4,5; C.1; D; and G.1,2

PERIOD OF PERFORMANCE: CO Approval – November 1, 2017

I. PURPOSE

This work assignment is a follow-on to work performed in the Base Period under Work Assignment 0-31. The purpose of this work assignment is to provide continued services to the U.S. Environmental Protection Agency's (hereinafter, EPA) National Center for Environmental Assessment (NCEA), within the Office of Research and Development (ORD). The specific purpose is to provide expert epidemiologic support for the development of Integrated Risk Information System (IRIS) scientific materials, including both qualitative and quantitative analyses and syntheses of human data and exposure information as identified in the contract performance work statement, Sections A (1 and 2); B (1, 2, 3, 4 and 5); C (1); D and G (1 and 2).

II. BACKGROUND

EPA's Integrated Risk Information System (IRIS) is a human health assessment program that evaluates quantitative and qualitative risk information on health effects that may result from exposure to environmental contaminants. When supported by available data, IRIS provides oral reference doses (RfDs) and inhalation reference concentrations (RfCs) for chronic non-cancer health effects, and oral slope factors and inhalation unit risks for carcinogenic effects. IRIS contains chemical-specific summaries of qualitative and quantitative health information in support of two steps of the risk assessment process, i.e., hazard identification and dose-response evaluation. By combining IRIS toxicity values with specific exposure information, government and other entities use IRIS to help characterize public health risks of chemical substances and thereby support risk management decisions designed to protect public health.

Assessments currently under development by the IRIS Program are listed on the IRIS website at https://cfpub.epa.gov/ncea/iris2/atoz.cfm; assessments that may be initiated in the coming year are identified in the IRIS multi-year agenda (https://www.epa.gov/iris/iris-agenda). Initiation of new assessments will depend on a number of factors, including regulatory/ programmatic priorities and availability of staff and other resources. Therefore, the IRIS Program will need to preserve flexibility in determining which assessments will require assistance during the period of performance of this Performance Work Statement (PWS).

III. SCOPE OF WORK: TASKS AND DELIVERABLES

Requirements Specific to this Work Assignment

Under this WA, an episode of work (aka "request") will be initiated by written Technical Direction (TD). Each request will clarify deadlines for delivering drafts and final work products. An initiating TD will identify the data and the specific Tasks (as outlined below) to be performed.

The Contractor shall prepare documents in the format specified in the current IRIS standard operating procedures and templates (to be provided by EPA). Recent examples of final and draft assessments for other chemicals may also serve as models. Documents shall be technically edited for format and grammar before being delivered to the EPA Work Assignment Manager (WAM).

The Contractor will be given an account in HERO (Health and Environmental Research Online), with access to scientific literature. Copyright law of the U.S. (Title 17 U.S. Code) governs the making of reproductions of copyrighted material. Section 107 of the copyright act instructs that, "the fair use of a copyrighted work for purposes such as ... research, is not an infringement of copyright." The Contractor is liable for any infringement of copyright. To set up the HERO account, the Contractor shall send an email to hero@epa.gov - and include the following information: Names, addresses, phone numbers, emails of all contractors needing HERO accounts, project name, start date and end date. The contractors will receive their HERO account information, with user documentation, within 3 business days.

HERO shall be used for performing literature searches. The literature search shall include, at a minimum, the following databases: PubMed, Web of Science, ToxNet; but may include others, as appropriate. The results from the literature search shall be submitted to HERO, as described in the user documentation. EPA will provide the PDFs through the HERO interface.

The Contractor shall use HERO for reference citation and bibliographic generation, as described in the user documentation.

The Contactor will develop and maintain internal documentation and data pertaining to all assumptions, data sources, databases, procedures, statistical analyses, and computer programming code, scripts, and software instructions used to support and execute EPA's requirements and deliverables, in order that results can be replicated. The Contactor will provide access to this internal documentation upon request by the EPA WAM or EPA Project Officer.

The Quality Assurance Project Plan (QAPP) developed under WA 0-31 during the Base Period will be used for this work assignment. The funding or scope of work is not expected to change for this WA. A kick-off conference call has been completed under WA 0-31 and thus is not required for this WA.

Task 1: Develop a Work Plan

The Contractor shall prepare a written work plan proposing a technical approach to the work assignment. The work plan shall outline how the work shall be performed and provide a list of deliverables and interim deliverables with the schedule for completion. In addition, the budget and staffing plan and a brief description of the qualifications of the key technical staff shall be included. The Contractor shall maintain communication with the WAM through weekly phone calls or email updates.

Deliverable Schedule: Work plan due in accordance with the contract.

Task 2: Quality Assurance Project Plan (QAPP) [completed in Base Period]

Task 3. Kick-off Conference Call [completed in Base Period]

Task 4: Manage, Identify and Recruit Expert Epidemiologists

The Contractor shall identify, recruit and manage expert epidemiologists ("experts") to develop sections of IRIS Toxicological Reviews and/or related materials. The Contractor shall be responsible for ensuring timely communication is passed between the EPA WAM and the experts so that technical clarification can be offered and interaction between EPA and the experts can occur as needed. The Contractor shall also ensure that the deliverables are provided to the EPA WAM in a timely manner.

EPA seeks to identify and recruit experts to develop several document sections/types for several different chemical assessments. These sections are discussed further in Task 5 within this WA, and they include:

1) Evaluation of exposure methods in epidemiological studies;

2) Study methods evaluations;

3) Evidence tables of specific health effects;

4) Graphical displays of evidence of specific health effects;

5) Other epidemiologic support (quantitative analysis, expert opinion, white papers, etc.).

EPA will provide guidance for the development of evidence tables and templates of the evidence and summary tables. The chemical assessments and related documents that will require assistance under this PWS will be clarified through technical direction.

The EPA assumes primary authorship in the writing process for all materials and contributing experts are listed in the final documents as appropriate. EPA will approve each of the experts performing work within two days of notification of a potential candidate.

Subtasks

1) Identify and Recruit Expert Epidemiologists

The Contractor shall identify and contact experts with a knowledge base that is aligned with the descriptions in each written TD. Each TD will specify the minimum/desired qualifications of the experts for that chemical assessment. The expertise needed will be specific to the broad field of epidemiology. Approximately 6 to 12 experts will be needed. Potential experts shall be asked to submit a bio-sketch to ensure they meet the minimum/desired qualifications, and EPA will notify the contractor of its concurrence with the selection.

2) Manage Expert Epidemiologists

The Contractor shall manage the recruited experts and ensure timely communication occurs between EPA and the experts. This shall involve setting up conference calls with the experts and EPA staff. In addition, the Contractor shall ensure that the written sections, comments and draft reviews are progressing on schedule and are delivered by the deadlines noted in this WA.

Deliverable Schedule: The schedule and specific expertise requested will be clarified within a TD.

Task 5. Complete Subtasks as Directed by EPA

The specific subtasks under this PWS, identified in Task 4, are described below. Specific clarification will be provided by the EPA WAM through technical direction. Technical Direction will be submitted individually for each chemical assessment or project, and the subtasks to be completed will be project-specific (i.e., not all of the subtasks will be completed for each project). EPA estimates that up to 6 work products related to one or more of the 5 primary tasks described below will be required over the period of performance of this PWS.

For some tasks (in particular subtasks 2 and 3 below), the Contractor may be asked to provide their work product using a database format. The database, and any necessary training or guidance on how to populate the database, will be provided to the Contractor by EPA.

1) Evaluation of exposure methods in epidemiological studies. The Contractor shall provide and manage experts to provide guidance and clarification regarding interpretation of exposure measures in epidemiological studies. This will include conducting a review of the reliability and validity of methods used in selected primary source studies, focusing on issues of nondifferential and differential misclassification. A tabular or draft synthesis of conclusions regarding different types of exposure measurement methods may be requested.

2) Study methods evaluation. The Contractor shall provide and manage experts to develop outcome-specific protocols to support consistent evaluation of the quality of individual

epidemiology studies consistent with the systematic review process. The purpose of this task is to evaluate studies with respect to potential methodological considerations that could affect the interpretation of or confidence in the results by applying a series of specific questions, and documenting study evaluation in tables. Experts may also be asked to apply protocols in evaluating study quality.

Study methods evaluations should be independent of considerations regarding the direction or magnitude of study results. Study methods evaluations will be performed at an early stage of assessment development, i.e., after identifying the relevant sources of primary data but before developing evidence tables and characterizing hazard associated with chemical exposure. EPA will provide templates or database for the Contractor to use in abstracting study information. The specific details as to what should be abstracted will be determined through consultation with the EPA WAM.

3) Evidence tables. The Contractor shall provide and manage experts to prepare evidence tables that summarize results from epidemiologic studies, consistent with the draft Handbook for IRIS Assessment Development and Elements of an Evidence Table (Appendix A). The Contractor shall also conduct quality assurance (QA) checks of evidence tables developed by the experts and/or provided by EPA that shall include the following: comparison of table entries to information from the original publication, checking conversions as appropriate (e.g., ppm to mg/m^3), confirming reported exposure ranges and effect measures, and inserting and verifying HERO links. The quality assurance checks should be performed by an expert that was not involved in the initial development of the table. EPA will provide the most current evidence table template or database for the Contractor to complete the task.

4) Graphical displays. The Contractor shall provide and manage experts to prepare graphical displays of results from epidemiologic studies. Approaches used for categorical exposure data (e.g., forest plots) and approaches used for quantitative data (e.g., representing magnitude of exposure or exposure contrast in relation to magnitude of effect) may be requested; the Contractor will provide expertise to develop or modify graphical displays ass needed. The Contractor shall also conduct quality assurance (QA) checks of the data used to generate graphical displays that shall include the following: comparison of data to information from the original publication, checking conversions as appropriate (e.g., ppm to mg/m^3), and inserting and verifying HERO links. The quality assurance checks should be performed by an expert that was not involved in the initial development of the graphical display.

5) Other epidemiologic support. The Contractor shall provide and manage experts to address other issues that may arise within the context of the review of epidemiologic studies. These issues may pertain to ascertainment of specific outcomes in epidemiology studies, assessment of potential for confounding (e.g., through knowledge of co-exposures in specific workplaces or communities), and other questions regarding bias. This may also include quantitative modeling of epidemiologic data.

Deliverable Schedule: The deliverable schedule will vary depending on the subtask(s) and chemical, and will depend on the amount and complexity of the information to be evaluated/summarized. The schedule will be clarified within a TD.

Task 6. Revision of Task 5 Deliverables

EPA will submit comments on the Task 5 deliverables. The Contractor shall provide and manage expert epidemiologic expertise to revise those deliverables based on EPA comments. The use of "redline" versions (track changes) of the document will be employed throughout the process. Tasks issued under this WA will be completed when all EPA comments have been considered and addressed, and may require multiple rounds of revision.

Deliverable Schedule: The deliverable schedule will vary depending on the subtask(s) and chemical. Unless otherwise specified in the TD, the Contractor will incorporate EPA comments within 7 days of receipt. The schedule will be clarified within the TD.

V. SCHEDULE OF DELIVERABLES

This schedule and deliverable dates specified under each Task above may be further clarified using written Technical Direction.

Task	**Schedule** (*all days are elapsed calendar days unless otherwise stated)
1. Develop a Work Plan	In accordance with contract
2. Quality Assurance Project Plan	Completed
3. Kick-off Conference Call	Completed
4. Manage, Identify and Recruit Expert Epidemiologists	To be clarified in written technical direction.
5. Complete Subtasks as Directed by EPA	To be clarified in written technical direction.
6. Revision of Task 5 Deliverables	To be clarified in written technical direction.

VI. NOTICE REGARDING GUIDANCE PROVIDED UNDER THIS PROJECT

Guidance is strictly limited to technical and analytical support. The Contractor shall not engage in activities of an inherently governmental nature such as the following:

(1) Formulation of Agency policy
(2) Selection of Agency priorities
(3) Development of Agency regulations

Should the Contractor receive any instruction from an EPA staff person that the Contractor ascertains to fall into any of these categories or goes beyond the scope of the contract or work assignment, the Contractor shall immediately contact the PO or WAM.

The Contractor shall also ensure that work under this work assignment does not contain any apparent or real personal or organizational conflict of interest. The Contractor shall certify that none exist at the time the proposal is submitted to EPA. The Contractor shall be responsible for obtaining a conflict of interest certification for any subcontractor services.

VII. SPECIAL CONDITIONS AND ASSUMPTIONS

The Contractor shall provide regular updates on progress and any issues that need to be resolved to the WAM by telephone or by email. Any technical directions made during informal discussions shall be issued promptly by the EPA WAM in writing (to include email).

VIII. EPA CONTACTS

EPA Work Assignment Manager (WAM)
Amanda S. Persad, PhD, DABT
919-541-9781
persad.amanda@epa.gov

Mailing Address:
U.S. EPA, ORD/NCEA (Mail Drop B-243-01)
RTP, NC 27711

Courier Deliveries:
U.S.E.P.A. Office of Research and Development, National Center for Environmental Assessment
MD B-243-01
4930 Page Road, Durham, NC 27703

EPA Alternate Work Assignment Manager (Alt-WAM)
Audrey Galizia, PhD
732-906-6887
galizia.audrey@epa.gov

Mailing Address:
U.S. EPA, ORD/NCEA (MS 215)
2890 Woodbridge Avenue
Edison, NJ 08837

Appendix A. Elements of an Evidence Table (for IRIS Assessments)

Evidence tables are an integral part of IRIS assessments. The first iteration of evidence tables is presented in Stage 1 of the IRIS process (Draft Development) as part of the "Preliminary Package" of public materials. Further iterations or versions of evidence tables are included at later stages of the IRIS process, and may vary depending upon the chemical database and needs of the specific assessment. General elements common to all evidence tables are described below; other elements (including those pertaining to study quality evaluation) may be added to the evidence tables and will vary in content and format to allow for the compilation of the most suitable approach for the respective body of information. These specific elements will be determined by the assessment team with consideration from the scoping and problem formulation process and members from the appropriate workgroup.

I. General elements:

All evidence tables should include the following:

- **Author, year and location of study**: reported in as much detail as possible – country/region, state, city, specific factories, etc.

Hayes et al. (1979) (United States)

- **Study description:** Present study design type, sample size, description of study participants and controls or reference group
    - Study design type: type of study with additional information as follows:
        - Cohort – length of follow up, % lost to follow up
        - Case-control – information on matching if performed
    - Sample size: the number of individuals or study units (e.g., couples, mother-child pairs) in various groups (may include: participation rate and data used in this derivation such as the number of participants recruited, number meeting selection criteria, number in final analysis/analyses, etc.)
    - Study population: This description should include:
        - Any relevant information on how the study population was selected (e.g., factory employment records), including any restrictions or inclusion/exclusions criteria (e.g., only workers with >1 year of job tenure)
        - Information on important demographic characteristics such as distribution of sex, age, and other outcome-specific factors (e.g., for pregnancy outcomes, may want to include parity; for lung cancer, may want to include smoking status)

Case-control study, 56 couples from assisted reproduction center, n=56 control couples (parents), mean age 39 years in both groups.

- **Exposure assessment:** Present how exposure was assessed (e.g., job exposure matrix, air sampling, etc). Also provide some measure of exposure levels (e.g., the mean and range of urinary concentrations of the chemical) for the study population, and/or for each group (e.g., the mean and range among the low and high exposed, or among cases and controls) if available.

- **Outcome assessment**: Present how was the outcome measured/evaluated (e.g., medical record, self-report, physician examination) and the degree that all cases were ascertained.

- **Analysis:** Present statistical methods (including any adjustment variables considered or used in the final analysis), and how results were evaluated. This should include details on how confounding was

addressed as well as a description of how statistical significance/precision was evaluated (e.g., use of confidence intervals and/or significance tests).

Proportionate mortality (cancer) ratios, using the U.S. general population to generate expected mortality, adjusted for age, time period of death

- **Results:** Present overall or stratified results as available and appropriate, including any corresponding confidence intervals and/or p-values. If no quantitative results are available, a statement on the results as reported by the author will be provided, making clear that this is the authors' report and not EPA's judgment of results.

Authors note a marked increase in the prevalence of respiratory irritation among exposed workers.

II. Other considerations for generation of evidence tables (not exhaustive):

- **Table Format**: Modifications may be made to the table format depending on the specific database and needs of the assessment. For example, evidence tables may have 2 or 3 columns with the additional column designated for 'Exposure.'
- **Reporting information**: If information is not available, state that it is not reported (e.g. "Outcome: cardiovascular disease (ICD codes not reported)" or "Follow-up time not reported"]
- **Process/Interim Drafts**: It is suggested that the contractor provide an interim draft early in the development process (with about 5 study entries) for review by the epidemiology workgroup. This will allow for early feedback to the contractor prior to the completion of the evidence tables. Further feedback and discussion between the contractor and the epidemiology workgroup is expected throughout the development and evolution of the evidence tables.

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 3-31

☐ Other ☒ Amendment Number: 000001

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-14-001	11/01/2013 To 10/31/2017	Epidemiologic Support for IRIS
	Base Option Period Number 3	

Contractor: ICF INCORPORATED, L.L.C.

Specify Section and paragraph of Contract SOW:

Purpose:
- ☐ Work Assignment
- ☒ Work Assignment Amendment
- ☐ Work Plan Approval
- ☐ Work Assignment Close-Out
- ☐ Incremental Funding

Period of Performance: From 11/01/2016 To 10/31/2017

Comments:
This amendment is to add the Alt. COR Audrey Galizia. All other terms and conditions remain unchanged.

☐ Superfund — Accounting and Appropriations Data — ☒ Non-Superfund

SFO (*Max 2*): ☐

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
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Authorized Work Assignment Ceiling

	Cost/Fee:	LOE:
Contract Period: 11/01/2013 To 10/31/2017		
This Action:		
Total:		

Work Plan / Cost Estimate Approvals

	Cost/Fee	LOE:
Contractor WP Dated:		
Cumulative Approved:		

Work Assignment Manager Name: Amanda Persad (Signature) (Date)	Branch/Mail Code: Phone Number: 919-541-9781 FAX Number:
Project Officer Name: Melissa Revely-Wilson (Signature) (Date)	Branch/Mail Code: Phone Number: 919-541-0207 FAX Number:
Other Agency Official Name: (Signature) (Date)	Branch/Mail Code: Phone Number: FAX Number:
Contracting Official Name: William Yates (Signature) (Date)	Branch/Mail Code: Phone Number: 513-487-2055 FAX Number:

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 3-40

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-14-001	11/01/2013 To 10/31/2017 Base Option Period Number 3	3-40 Microbial risk assess

Contractor: ICF INCORPORATED, L.L.C.

Specify Section and paragraph of Contract SOW:

Purpose:
- ☒ Work Assignment
- ☐ Work Assignment Amendment
- ☐ Work Plan Approval
- ☐ Work Assignment Close-Out
- ☐ Incremental Funding

Period of Performance: From 11/01/2016 To 10/31/2017

Comments:

☐ Superfund — Accounting and Appropriations Data — ☒ Non-Superfund

SFO (*Max 2*): ☐

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
2										
3										
4										
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Authorized Work Assignment Ceiling

	Cost/Fee	LOE
Contract Period: 11/01/2013 To 10/31/2017		
This Action:		
Total:		

Work Plan / Cost Estimate Approvals

	Cost/Fee	LOE
Contractor WP Dated:		
Cumulative Approved:		

Work Assignment Manager Name: Eric Rhodes (Signature) (Date)	Branch/Mail Code: Phone Number: 513-569-7308 FAX Number:
Project Officer Name: Melissa Revely-Wilson (Signature) (Date)	Branch/Mail Code: Phone Number: 919-541-0207 FAX Number:
Other Agency Official Name (Signature) (Date)	Branch/Mail Code: Phone Number: FAX Number:
Contracting Official Name: William Yates (Signature) (Date)	Branch/Mail Code: Phone Number: 513-487-2055 FAX Number:

PERFORMANCE WORK STATEMENT
CONTRACT NO. EP-C-14-001
WA 3-40

TITLE: Microbial risk assessment methodology development and application

Specify Section & Paragraph SOW: B2. Support research, development, and application of new risk assessment methods suitable for either conducting or evaluating cumulative risk, microbial risk, mixtures risk, dose-response assessment (including extrapolation to low dose), exposure assessment, and relevant uncertainty analysis.

I. OBJECTIVES

The main objectives of this Work Assignment (WA) are to determine:

- Complete publication regarding physiological responses from Bacillus anthracis exposure in rabbits.
- Draft, revise reports, and/or journal articles regarding exposure assessment pathways analysis for high consequence pathogens.

II. BACKGROUND

The U.S. Environmental Protection Agency's (EPA's) National Homeland Security Research Center (NHSRC) was established to conduct research in support of indoor/outdoor decontamination and water security. Specifically, NHSRC is responsible for assessing potential exposures associated with the intentional or accidental release of hazardous and toxic materials including chemical, biological, and nuclear agents. NHSRC is currently developing tools, technologies, and methods to aid and support this effort. One of the highest priorities of NHSRC is the applications of risk assessment methodologies that can be utilized to support decision making regarding cleanup goals, treatment technology efficacies, detection limits, and waste management options during biological contamination incidents. One exposure scenario of concern is the potential for exposure to possible residual biological contamination after buildings or other areas are cleared for re-entry. Given the potentially unique hazard posed by repeated low-level exposures to Bacillus anthracis spores, these assessments are challenged by the identification of appropriate microbial risk assessment models and methodologies.

NOTE: This work assignment is a follow-on to work performed in the Year 2 Option Period under Work Assignment # 2-40. The work continues from Task 1 through Task 4 during this Year 3 Option Period under Work Assignment 3-40. This PWS describes only Tasks 1-4.

III. TASKS

Task 1: <u>Workplan</u>

The contractor shall generate a workplan describing how tasks 2-4 shall be performed. The workplan shall include the overall project purpose, scope, and approach. Each task shall be described in detail including the

specifics of the personnel projected to complete each task indicating the level of expertise required, personnel labor hours, timelines to complete each task, projected costs of each task, equipment and supplies required, facilities to be used, specific standard operating procedures (SOPs) (or location of SOPs on-site if considered proprietary business information), standards and controls used for compliance with quality assurance, data analysis and calculations to be utilized, safety considerations, and the risks associated with each task along with proposed mitigations. The workplan shall outline the tasks and subtasks along with timelines projected for completion of each task and task inter-relationships. The contractor shall ensure adherence in the workplan to the existing approved Quality Assurance Project Plan developed under the previous year funding (WA1-40).

Deliverables: Workplan

Task 2: Exposure Assessment Pathways Analysis Report and/or Journal Article

If determined by the WA-COR to exercise this task, the contractor shall develop some conceptual models and analysis plan for bio-contaminated wastewater human exposure pathways from the point of collection until the release back into the environment. This would include modeling the wastewater through the wastewater treatment plants and determining if there are any viable exposure pathways of concern given high consequence agent contaminations such as Ebola and *Bacillus anthracis* spores.

Deliverable: Exposure Assessment Pathways Analysis Report (peer review draft, management review draft and response to comment document report and tables), Peer review publication to scientific journal (peer review draft, management review draft and response to comment document report and tables), technical brief (peer review draft, management review draft and response to comment document report and tables). Peer review publication to scientific journal

Performance Standard: The contractor shall provide the final analysis report within 10 months after approval of work plan if determined necessary by the WA-COR. The contractor shall provide the draft peer reviewed publication for management review within 6 months after approval of work plan if determined necessary by the WA-COR. The contractor shall revise journal articles within 1 month after receiving journal comments. The contractor shall provide a technical brief within 10 months after approval of work plan if determined necessary by the WA-COR.

Task 3: Rabbit Physiological Characterization Paper

The contractor shall revise and respond to comments per journal reviews for journal articles summarizing rabbit physiological characteristics.

Deliverable: Revised journal articles

Performance Standard: The contractor shall revise journal articles within 1 month after receiving journal comments.

Task 4: Communications and Progress Reports

Bi-weekly conference calls shall be conducted between the WAM and the contractor to keep the project team updated on tasks progress and completion as well as any unanticipated issues.

Monthly Reports: Every month, the contractor shall submit reports detailing the overall project status, including a narrative description of the work, preliminary conclusions, and path forward. The monthly report shall provide a concise summary of significant issues, changes in project status, publications, presentations,

patents, results of travel, completion of scheduled milestones, project delays and other accomplishments/issues during the reporting period. This report shall also include the financial status at the end of each month (funds received, commitments, obligations, and expenditures) with a graph of the actual and projected obligations and expenditures for the current fiscal year, and new digital pictures relevant to the project.

The contractor shall provide monthly a list of all documents prepared about work done under contract funding to include internal technical reports and presentations, external technical reports and presentations, and responses to requests, whether in written or electronic form, for information from external sources. Copies of such information shall be made available to the WAM on request within two weeks of the request.
The contractor shall also submit combined technical and financial bi-weekly reports through email briefly and concisely updating task progress, changes in project status, significant issues, and financial status.

Outside Presentations of Project Research: Attendance at research meetings to present project results should be limited to the contractor project lead and technical staff on an as needed basis as deemed appropriate by prior consent of WAM. All documents or presentations associated with this project shall be cleared through WAM prior to submission to outside sources as described below. Travel costs associated with this project shall be approved by WAM prior to confirming and registering for meetings.

Reporting Requirements: All contractor generated documents and reports including task reports, interim reports, and task deliverable reports shall be considered draft upon first submission to WAM. WAM shall provide comments back to the contractor within 3 weeks of submission. The contractor shall provide a final version back to WAM with responses and dispositions of comments.

All references cited in submitted reports and deliverables to WAM shall be provided to WAM either as a pdf copy in electronic form on disk or hardcopy.

The contractor shall ensure that all documents prepared under this WA are technically accurate, defensible, free of errors (e.g., data entry, methodology), and editorially correct (e.g., free of typographic and grammatical errors). All supporting information shall be referenced and made available if requested.

The contractor shall be responsible for information and data collection, storage, processing, validation, calculations, reporting, and delivery to WAM. The contractor shall provide document preparation and revision and ensure that the products are responsive, timely, and of high quality to meet the requirements of the Agency. All documents prepared under these tasks shall respond to the issues identified by WAM, and include supporting references and rationale for the recommendations and conclusions given.

All written information (reports, reviewer comments and meeting reports) shall be prepared using Microsoft Word format. Any spreadsheet or database data shall be in Microsoft Office format compatible with EPA software. The literature resources shall be provided in Adobe Acrobat format (i.e., pdf file) or paper hard copy. The contractor shall provide a CD containing all data and documentation along with three hard copies of the final task deliverable reports and one copy of any references cited in the documents. The documents shall be formatted in 12-point Times New Roman Font and 1-1/2 line spacing.

Deliverables: Bi-weekly conference calls, monthly reports, and periodic meetings.

Performance Standard: The contractor shall participate in bi-weekly conference calls and meetings as needed and submit bi-weekly emails and monthly reports.

IV. DELIVERABLES AND QUALITY ASSURANCE SURVEILLANCE

Task	Deliverable	Performance Standard	Monitoring Method

1	Work Plan	Contractor shall provide the completed Work Plan within 30 days of award	WA-COR shall document whether receipt of Work Plan is timely and acceptable, and provide technical revisions as required
	Revised Work Plan	Contractor shall revise Work Plan if required and submit final Work Plan no more than 30 days after receipt of revisions	WA-COR shall document receipt of revised Work Plan, and ensure that is timely and technically acceptable
2	Exposure Assessment Pathways Analysis	Contractor shall provide the draft Exposure Assessment Pathways Analysis within 10 months after approval of the workplan	WA-COR shall document whether receipt of Analysis is timely and acceptable, and provide technical revisions as required
	Revised Exposure Assessment Pathways Analysis	Contractor shall revise Analysis if required and submit final document no more than 30 days after receipt of revisions	WA-COR shall document receipt of revised Analysis, and ensure that is timely and technically acceptable
	Journal Article	Contractor shall provide the draft journal article within 6 months after approval of the workplan	WA-COR shall document whether receipt of Analysis is timely and acceptable, and provide technical revisions as required
	Journal Article revisions	Contractor shall revise journal articles within 1 month after receiving EPA comments	WA-COR shall document the receipt of journal article revisions, and ensure that they are timely and technically acceptable and provide technical comments as appropriate
	Technical Brief	Contractor shall provide the draft technical brief within 10 months after approval of the workplan	WA-COR shall document whether receipt of Analysis is timely and acceptable, and provide technical revisions as required
	Technical Brief revisions	Contractor shall revise the technical brief within 1 month after receiving EPA comments	WA-COR shall document the receipt of journal article revisions, and ensure that they are timely and technically acceptable and provide technical comments as appropriate
3	Journal Article Revisions	Contractor shall revise journal articles within 1 month after receiving EPA comments	WA-COR shall document the receipt of journal article revisions, and ensure that they are timely and technically acceptable and provide technical comments as appropriate
4	Bi-Weekly Conference Calls	Contractor shall participate in bi-weekly conference calls with the WAM briefly updating project progress	WAM shall participate in these calls to identify any issues to be addressed in the research or future reports
	Monthly Reports	Contractor shall prepare monthly reports as specified in the statement of work	WAM shall document receipt of monthly reports and ensure that these are timely and acceptable
	Meetings with WAM	Contractor shall have periodic meetings with the WAM as needed	WAM shall participate in these meetings and identify any issues to be addressed

VI. INTELLECTUAL PROPERTY

All methods, models, and assays developed by the contractor and/or provided to the contractor under this WA are the intellectual property of the NHSRC and Department of Homeland Security (DHS). All data collected and analyzed under this WA are the intellectual property of the NHSRC and DHS.

Authorship on research presentations associated with this project including, but not limited to, abstracts, posters, PowerPoint presentations, and publications shall be agreed upon prior to submission for consideration by any external organization. Authorship should reflect 1) contribution through project conception and design, 2) data acquisition, 3) data interpretation and analysis, 4) presentation preparation.

VII. NOTICE REGARDING GUIDANCE PROVIDED UNDER THIS WORK ASSIGNMENT

Guidance is strictly limited to technical and analytical support. The contractor shall not engage in activities of an inherent governmental nature such as the following:

1. Formulation of Agency policy
2. Selection of Agency priorities
3. Development of Agency regulations

Should the contractor receive any instruction from an EPA staff person that the contractor ascertains to fall into any of these categories or goes beyond the scope of this WA, the contractor should immediately contact the EPA Contracting Officer.

The contractor shall also ensure that work under this WA does not contain any apparent or real personal or organizational conflicts of interest. The contractor shall certify that none exist with its workplan.

VIII. WORK ASSIGNMENT MANAGER (WAM) AND ALTERNATE WAM

WAM:
Eric Rhodes, Ph.D.
U.S. EPA OFFICE OF RESEARCH AND DEVELOPMENT
National Homeland Security Research Center
26 W. Martin Luther King Drive (NG-16)
Cincinnati, OH 45268
Work 513/569-7308
Rhodes.Eric@epa.gov

Alternate WAM:
Sarah Taft, Ph.D.
U.S. EPA OFFICE OF RESEARCH AND DEVELOPMENT
National Homeland Security Research Center
26 W. Martin Luther King Drive (NG-16)
Cincinnati, OH 45268
Work 513/569-7037

Cell 513/288-5460
Taft.Sarah@epa.gov

APPENDIX A

EPA's Quality System Website: http://www.epa.gov/quality

EPA's Requirements and Guidance Documents: http://www.epa.gov/quality/qa_docs.html

EPA's Quality System Website: http://www.epa.gov/quality/qs-docs/r5-final.pdf

In accordance with EPA Order 5260.1 A2, conformance to ANSI/ASQC E4 must be demonstrated by submitting the quality documentation described herein. All Quality documentation shall be submitted to the Government for review. The Government will review and return the quality documentation, with comments, and indicate approval or disapproval. If the quality documentation is not approved, it must be revised to address all comments and shall be resubmitted to the Government for approval. Work involving environmental data collection, generation, use, or reporting shall not commence until the Government has approved the quality documentation. The Quality Assurance Project Plan (QAPP) shall be submitted to the Government at least thirty (30) days prior to the beginning of any environmental data gathering or generation activity in order to allow sufficient time for review and revisions to be completed. After the Government has approved the quality documentation, the Contractor shall also implement it as written and approved by the Government.

NHSRC's Quality System Specifications for Extramural Actions –

These requirements typically pertain to single project efforts. The five specifications are:

(1) a description of the organization's Quality System (QS) and information regarding how this QS is documented, communicated and implemented;

(2) an organizational chart showing the position of the QA function;

(3) delineation of the authority and responsibilities of the QA function;

(4) the background and experience of the QA personnel who will be assigned to the project; and

(5) the organization's general approach for accomplishing the QA specifications in the SOW.

NHSRC QA Requirements/Definitions List

Category Level Designations (determines the level of QA required):

☐ **Category I Project** - applicable to studies performed to generate data used for enforcement activities, litigation, or research project involving human subjects. The QAPP shall address all elements listed in "EPA Requirements for QA Project Plans, EPA QA/R-5.

☐ **Category II Project** - applicable to studies performed to generate data used in support of the development of environmental regulations or standards. The QAPP shall address all elements listed in "EPA Requirements for QA Project Plans, EPA QA/R-5.

☒ **Category III Project** - applicable to projects involving applied research or technology evaluations. The QAPP shall address the applicable sections of "EPA Requirements for QA Project Plans, EPA QA/R-5 as outlined in the **NHSRC's QMP: QAPP** requirements for the specific project type (see below).

☐ **Category IV Project** - applicable to projects involving basic research or preliminary data gathering activities. The QAPP shall address the applicable sections of "EPA Requirements for QA Project Plans, EPA QA/R-5 as outlined in the **NHSRC's QMP QAPP** requirements for the specific project type (see below).

Project Types:

These outlines of NHSRC's QAPP Requirements for various project types, from Appendix B of the NHSRC QMP (except where otherwise noted), are condensed from typically applicable sections of R-5 (EPA Requirements for QA Project Plans) and are intended to serve as a starting point when preparing a QAPP. These lists and their format may not fit every research scenario and QAPPs must conform to applicable sections of R-5 in a way that fully describes the research plan and appropriate QA and QC measures to ensure that the data are of adequate quality and quantity to fit their intended purpose.

☐ **Applied Research Project** - pertains to a study performed to generate data to demonstrate the performance of accepted processes or technologies under defined conditions. These studies are often pilot- or field-scale. The QAPP shall address all requirements listed in "QAPP Requirements for Applied Research Projects" from Appendix B of the NHSRC QMP.

☐ **Basic Research Project** - pertains to a study performed to generate data used to evaluate unproven theories, processes, or technologies. These studies are often bench-scale. The QAPP shall address all requirements listed in "QAPP Requirements for Basic Research Projects" from Appendix B of the NHSRC QMP.

☐ **Design, Construction, and/or Operation of Environmental Technology Project** - pertains to environmental technology designed, constructed and/or operated by and/or for EPA. The QAPP shall address requirements in the EPA Quality System document "Guidance on Quality Assurance for Environmental Technology Design, Construction, and Operation" G-11, at http://www.epa.gov/quality/QS-docs/g11-final-05.pdf. For additional information, you may refer to Part C of "Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology," ANSI/ASQC E4-1994, American Society for Quality Control, Milwaukee, WI, January 1995.

☐ **Geospatial Data Quality Assurance Project** - pertains to data collection; data processing and analysis; and data validation of geospatial applications. The QAPP shall address requirements in the EPA Quality System document "Guidance for Geospatial Data Quality Assurance Project Plans" G-5S at http://www.epa.gov/quality/QS-docs/g5g-final-05.pdf.

☐ **Method Development Project** - pertains to situations where there is no existing standard method, or a standard method needs to be significantly modified for a specific application. The QAPP shall address all requirements listed in "QAPP Requirements for Method Development Projects" from Appendix B of the NHSRC QMP.

☐ **Model Development Project** - includes all types of mathematical models including static, dynamic, deterministic, stochastic, mechanistic, empirical, etc. The QAPP shall address requirements in the EPA Quality System document "Guidance for Quality Assurance Project Plans for Modeling."

☐ **Sampling and Analysis Project** - pertains to the collection and analysis of samples with no objectives other than to provide characterization or monitoring information. The QAPP shall address all requirements listed in "QAPP Requirements for Sampling and Analysis Projects" from Appendix B of the NHSRC QMP.

☒ **Secondary Data Project** - pertains to environmental data collected from other sources, by or for EPA, that are used for purposes other than those originally intended. Sources may include: literature, industry surveys, compilations from computerized databases and information systems, and computerized or mathematical models of environmental processes. The QAPP shall address all requirements listed in "QAPP Requirements for Secondary Data Projects" from Appendix B of the NHSRC QMP.

☐ **Software Development and Data Management Project** - pertains to software development, software/hardware systems development, database design and maintenance, data validation and verification systems. The QAPP shall address all requirements listed in "QAPP Requirements for Software Development Projects" from Appendix B of the NHSRC QMP.

Definitions:

Environmental Data - These are any measurement or information that describe environmental processes, location, or conditions; ecological or health effects directly from measurements, produced from software and models, and compiled from other sources such as data bases or the literature. For EPA, environmental data include information collected directly from measurements, produced from software and models, and compiled from other sources such as data bases or literature.

Incremental Funding - Incremental funding is partial funding, no new work.

Quality Assurance (QA) - Quality assurance is a system of management activities to ensure that a process, item, or service is of the type and quality needed by the customer. It deals with setting policy and running an administrative system of management controls that cover planning, implementation, and review of data collection activities and the use of data in decision making. Quality assurance is just one part of a quality system.

Quality Assurance Project Plan (QAPP) - A QAPP is a document that describes the necessary quality assurance, quality control, and other technical activities that must be implemented to ensure that the results of the work performed will satisfy the stated performance criteria. A QAPP documents project-specific information.

Quality Control (QC) - Quality control is a technical function that includes all the scientific precautions, such as calibrations and duplications, which are needed to acquire data of known and adequate quality.

Quality Management Plan (QMP) - A QMP is a document that describes an organization's/program's quality system in terms of the organizational structure, policy and procedures, functional responsibilities of management and staff, lines of authority, and required interfaces for those planning, implementing, documenting, and assessing all activities conducted. A QMP documents the overall organization/program, and is primarily applicable to multi-year, multi-project efforts. An organization's/program's QMP shall address all elements listed in the "Requirements for Quality Management Plans" in Appendix B of the NHSRC QMP.

Quality System - A quality system is the means by which an organization manages its quality aspects in a systematic, organized manner and provides a framework for planning, implementing, and assessing work performed by an organization and for carrying out required quality assurance and quality control activities.

R-2. EPA Requirements for Quality Management Plans (EPA/240/B-01/002) March, 2001
http://www.epa.gov/quality/QS-docs/r2-final.pdf.

R-5. EPA Requirements for Quality Management Plans (EPA/240/B-01/002) March, 2001
http://www.epa.gov/quality/QS-docs/r5-final.pdf.

Substantive Change - Substantive change is any change in an activity that may alter the quality of data being used, generated, or gathered.

Technical Lead Person (TLP) - This person is technically responsible for the project. For extramural contract work, the TLP is typically the contracting officer's representative (COR). For intramural work, the TLP is typically the Principal Investigator.

Abbreviations

COR	Contracting Officer's Representative
NHSRC	National Homeland Security Research Center
NRMRL	National Risk Management Research Laboratory
QA ID	Quality Assurance Identification
QAPP	Quality Assurance Project Plan
QS	Quality System
TLP	Technical Lead Person
IAG	Interagency Agreement
QA	Quality Assurance
QAM	Quality Assurance Manager
QMP	Quality Management Plan
SOW	Statement of Work
CRADA	Cooperative Research & Development Agreement

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 3-40

☐ Other ☒ Amendment Number: 000001

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-14-001	11/01/2013 To 10/31/2017 Base X Option Period Number	

Contractor: ICF INCORPORATED, L.L.C.

Specify Section and paragraph of Contract SOW:

Purpose:
- ☐ Work Assignment
- ☒ Work Assignment Amendment
- ☐ Work Plan Approval
- ☐ Work Assignment Close-Out
- ☐ Incremental Funding

Period of Performance: From 11/01/2016 To 10/31/2017

Comments:
This amendment (001) changes the Work Assignment Manager (WAM) from ERIC RHODES to SANDIP CHATTOPADHYAY, all other terms and conditions remain unchanged and in full effect.

☐ Superfund — Accounting and Appropriations Data — ☒ Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (*Max 2*) ☐

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
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Authorized Work Assignment Ceiling

	Cost/Fee	LOE
Contract Period: 11/01/2013 To 10/31/2017		
This Action:		
Total:		

Work Plan / Cost Estimate Approvals

	Cost/Fee	LOE
Contractor WP Dated:		
Cumulative Approved:		

Work Assignment Manager Name: Sandip Chattopadhyay (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	513-569-7549
	FAX Number:	
Project Officer Name: Joseph W. Hicks (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	202-564-1449
	FAX Number:	
Other Agency Official Name (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	
	FAX Number:	
Contracting Official Name: William Yates (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	513-487-2055
	FAX Number:	

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 3-44

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-14-001	11/01/2013 To 10/31/2017	International Decontamination
	Base Option Period Number 3	

Contractor	Specify Section and paragraph of Contract SOW
ICF INCORPORATED, L.L.C.	E2

Purpose:
- [X] Work Assignment
- [ ] Work Assignment Amendment
- [ ] Work Plan Approval
- [ ] Work Assignment Close-Out
- [ ] Incremental Funding

Period of Performance: From 11/01/2016 To 10/31/2017

Comments:
Support to the 2016 US EPA International Decontamination Research and Development Conference

☐ Superfund — Accounting and Appropriations Data — [X] Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (*Max 2*) ☐

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
2										
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Authorized Work Assignment Ceiling

Contract Period: 11/01/2013 To 10/31/2017 — Cost/Fee: — LOE:

This Action:

Total:

Work Plan / Cost Estimate Approvals

Contractor WP Dated: — Cost/Fee — LOE:

Cumulative Approved: — Cost/Fee — LOE:

Work Assignment Manager Name: Lukas Oudejans (Signature) (Date)	Branch/Mail Code: Phone Number: 919-541-2973 FAX Number:
Project Officer Name: Melissa Revely-Wilson (Signature) (Date)	Branch/Mail Code: Phone Number: 919-541-0207 FAX Number:
Other Agency Official Name: (Signature) (Date)	Branch/Mail Code: Phone Number: FAX Number:
Contracting Official Name: William Yates (Signature) (Date)	Branch/Mail Code: Phone Number: 513-487-2055 FAX Number:

PERFORMANCE WORK STATEMENT
CONTRACT NO. EP-C-14-001
WA 3-44

TITLE: Support to the 2016 US EPA International Decontamination Research and Development Conference

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Specify Section & Paragraph SOW: E2, Risk Assessment Support; Administration and Technical Support for Meetings

PERIOD OF PERFORMANCE: CO award to 10/31/17

I. PURPOSE

The purpose of this Work Assignment is to provide services to the U.S. Environmental Protection Agency's (hereinafter EPA or Agency) for administrative and technical support to the 2016 US EPA International Decontamination Research and Development Conference, hosted by EPA's National Homeland Security Research Center (NHSRC).

The desired goals of the conference are the following:

- To bring together researchers, responders, U.S. and international government and private stakeholders in CBR remediation and recovery preparedness;
- To facilitate the exchange of information on scientific endeavors, including applied research, field demonstrations, guidance and tool development and field applications related to CBR remediation issues; and,
- To demonstrate the connection between basic or fundamental decontamination research and applied research, as well as applied research and effective field application.

The work assignment has three major components: (1) the preparation and (2) implementation of a three day conference to take place on November 1-3, 2016, at the EPA RTP campus in North Carolina; (3) the preparation of a post-conference report that compiles the abstracts and presentations along with an executive summary of the conference. This work assignment includes the following major deliverables:

1. Assistance and coordination with a three day conference as noted in the tasks.
2. Administrative and Technical support for the three day Decontamination R&D Conference.
3. Assistance with plenary speaker and up to three other outside participants.
4. Post-conference summary report.

Under previous WA 2-44, tasks related to the preparation of the conference were completed. This WA covers tasks to be executed during the conference and post conference activities.

II. BACKGROUND

Since 2004, NHSRC has organized and hosted an international conference on decontamination research and development. Decontamination is one of the critical challenges that the United States and EPA would face in recovering from a major chemical, biological, or radiological incident.

The conference is designed to facilitate presentation, discussion, and further collaboration on research and development focused on an all-hazards approach to cleaning up contaminated buildings (both interior and exterior), infrastructure, and other areas/materials. The conference continues to focus strongly on matters involving chemical, biological, and radiological (CBR) threat agents but also include "all hazards' elements.

Topics of interest for this conference include:
- New research data, or field activities and large scale demonstrations related to the detection and decontamination of biological (including agricultural threat agents and biotoxins), chemical, and radiological threat agents in indoor (in facilities) or outdoor areas/materials
- Cross cutting topics related to restoration including: clean-up levels/risk assessment, exposure assessment, sampling/analysis of threat agents, fate/transport/containment, material compatibility with decontamination processes, tool and guidance development, waste management of threat agent-contaminated materials, water/wastewater decontamination, and systems approach to response and regulatory issues.

Invitees include persons involved in CBR remediation and recovery research, individuals such as EPA On-Scene Coordinators who conduct remediation activities, people involved in setting policy related to CBR decontamination in the U.S. and abroad, as well as individuals from academia and industry.

III. STATEMENT OF WORK

Task 1: Establish Communication

Within 3 days of start date of this WA, the Contractor shall schedule a conference call (not to exceed 1 hour) with the WAM and appropriate contractor staff to clarify outstanding questions and confirm the schedule and specific tasks.

Task 2: Work Plan, Staffing Plan, and Quality Assurance Project Plan (QAPP)

The Contractor shall prepare a Technical Work Plan describing how the work outlined in this Performance Work Statement will be performed, including deliverables, a schedule, budget, and level of effort. The Contractor shall also prepare a Staffing Plan, which shall be submitted as part of the Work Plan, which shows assigned personnel by task and the qualifications of the proposed personnel. The Contractor shall provide expertise in administrative and technical support to a conference.

Task 3: PRE-CONFERENCE PREPARATION

Task 3.1. Conference Abstract Collection:

This task was completed during the previous option period

Task 3.2. Pre-registering Conference Participants:

This task was completed during the previous option period

Task 3.3. Other Pre-Meeting Logistical Activities (e.g. Coordination with speakers, securing on-site Audio/Visual, IT support):

This task was completed during the previous option period

Task 3.4. Preparing Conference Materials:

This task was completed during the previous option period

TASK 4: DURING-CONFERENCE RESPONSIBILITIES

Task 4.1. Conference Registrations:

The on-site Contractor support shall include manning the registration table, providing participant name tags and conference information packets, providing EPA handouts and allowing space for other information provided by speakers ahead of time and signing in registrants.

Task 4.2. Conference IT Logistics:

The EPA will provide laptop computers. The Contractor shall coordinate with the WAM to ensure that all presentations are loaded onto EPA computer. The Contractor shall provide technical support during the conference in coordination with the EPA AV support staff.

TASK 5: CONFERENCE INVITED SPEAKER TRAVEL

Task 5.1. Invited Speaker Travel:

This task was initiated during the previous option period. The Contractor shall continue to coordinate logistics for 1 international and up to 3 domestic scientists and pay for their travel. The Contractor shall anticipate that the speakers will attend the entire Conference.

TASK 6: POST-CONFERENCE

Task 6.1. Conference Executive Summary:

The Contractor shall prepare an executive summary of the conference that can function as a standalone document. This summary shall include the Keynote Speaker's presentation and question and answer session plus highlights from the other sessions.

Task 6.2. Conference Report:

The Contractor shall prepare an electronic document that compiles all presentations, abstracts, speaker question and answer sessions and the executive summary developed under Task 6.1 into a single PDF and Microsoft Word file. The draft conference report will include the final agenda, a complete list of actual attendees and their contact information as agreed upon during the registration process as appendices.

Task 6.2. Power Point Presentations:

The Contractor shall post the released presentations onto an ftp-like server that can be accessed by the conference participants.

IV. ANTICIPATED DELIVERABLES

All products by the Contractor must be of high quality, written in a clear concise style, with a logical organization and presentation. Deliverables shall be provided to EPA in electronic formats compatible with EPA-supported software (e.g., MS Office 2013 (or later) spreadsheets and documents).

V. DELIVERABLES AND SCHEDULE

Task 1. Initial Conference Call	3 days after award of Work Assignment
Task 2. Work, Staffing Plan	20 days after award
Task 6.1 Draft Executive Summary	Within 6 weeks of conference conclusion
Final Executive Summary	Within 10 business days after receipts EPA comments to draft
Task 6.2 Draft Conference Report	Within 3 months of conference conclusion
Final Conference Report	Within 20 business days after receipts EPA comments to draft

Note: All days are calendar days.

VI. MANAGEMENT CONTROLS

1. All deliverables shall be reviewed for conformance to the requirements of this work assignment before being approved as final.

2. The contractor shall comply with other applicable requirements for final work assignment reports stipulated in contract.

VII. NOTICE REGARDING GUIDANCE PROVIDED UNDER THIS PROJECT

Guidance is strictly limited to technical and analytical support. The contractor shall not engage in activities of an inherent governmental nature such as the following:

(1) Formulation of Agency policy
(2) Selection of Agency priorities
(3) Development of Agency regulations

Should the contractor receive any instruction from an EPA staff person that the contractor ascertains to fall into any of these categories or goes beyond the scope of the contract or work assignment, the contractor shall immediately contact the PO, WAM or CO.

VIII. SPECIAL CONDITIONS AND ASSUMPTIONS

The contractor shall hold a conference call with the EPA WAM at the initiation of the work assignment, and shall provide a bi-weekly update to the WAM by telephone for the duration of the work assignment, in addition to the standard reporting requirements of the contract.

IX. EPA CONTACT INFORMATION

Copies of all correspondence pertaining to the performance of this work assignment shall be sent to the PO.

Work Assignment Manager (WAM):

Lukas Oudejans
U.S. EPA, ORD/NHSRC
109 TW Alexander Dr.
Research Triangle Park, NC 27711
919-541-2973
oudejans.lukas@epa.gov

Alternate WAM:

Tanya Medley
U.S. EPA, ORD/NHSRC
109 TW Alexander Dr.
Research Triangle Park, NC 27711
919-541-2336
medley.tanya@epa.gov

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 3-46

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-14-001	11/01/2013 To 10/31/2017 Base Option Period Number 3	Utero exposures

Contractor: ICF INCORPORATED, L.L.C.

Specify Section and paragraph of Contract SOW:

Purpose:
- [X] Work Assignment
- [ ] Work Assignment Amendment
- [ ] Work Plan Approval
- [ ] Work Assignment Close-Out
- [ ] Incremental Funding

Period of Performance: From 11/01/2016 To 10/31/2017

Comments:

☐ Superfund — Accounting and Appropriations Data — [X] Non-Superfund

SFO (*Max 2*): ☐

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

	Cost/Fee:	LOE:
Contract Period: 11/01/2013 To 10/31/2017		
This Action:		
Total:		

Work Plan / Cost Estimate Approvals

	Cost/Fee	LOE:
Contractor WP Dated:		
Cumulative Approved:		

Work Assignment Manager Name: Andrew Hotchkiss (Signature) (Date)	Branch/Mail Code:	
	Phone Number: 919-541-4164	
	FAX Number:	
Project Officer Name: Melissa Revely-Wilson (Signature) (Date)	Branch/Mail Code:	
	Phone Number: 919-541-0207	
	FAX Number:	
Other Agency Official Name (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	
	FAX Number:	
Contracting Official Name: William Yates (Signature) (Date)	Branch/Mail Code:	
	Phone Number: 513-487-2055	
	FAX Number:	

PERFORMANCE WORK STATEMENT
CONTRACT NO. EP-C-14-001
Amendment to WA 2-46 carried over to WA 3-46

TITLE: Literature search and analysis of available epidemiological data available for human health effects observed due to in utero exposures to environmental pollutants.

Specify Section & Paragraph SOW: Assessment Issues and Documents 1. Human Health Assessment Documents

PERIOD OF PERFORMANCE: CO Award thru 10/31/2017

I. PURPOSE

The purpose of this Work Assignment is to provide services to the U.S. Environmental Protection Agency's (hereinafter EPA or Agency) National Center for Environmental Assessment (NCEA), Office of Research and Development (ORD), for conducting literature searches and subsequent analyses of human epidemiological studies that have observed health effects due to in utero exposure to environmental pollutants. The development of project will include the development of literature searches, systematic review (including risk of bias) evidence tables, identification of biomarkers of exposure and analyses of available NHANES data, derivation of points of departure (PODs) for select studies, characterization of the exposure distribution for women of reproductive age, evaluation of mechanistic data to provide insight into possible adverse outcome pathways (AOPs).

II. BACKGROUND

The importance of in utero exposures relative to environmental pollutants has resulted in numerous epidemiological studies characterizing the association between this critical time window of exposure and health effects resulting in later life. Based upon a brief literature search, epidemiological studies have characterized relationships between health effects and environmental pollutants including polybrominated diphenyl ether (Chen et al., 2013; Eskenazi, et al., 2013;), polyaromatic hydrocarbons (PAHs; Perera et al., 2012; 2009), arsenic (Graziano et al., 2014; Nadeau et al., 2014; Recio-Vega et al., 2014; Steinmaus et al., 2014), lead (Nye et al., 2014), methylmercury (Yorifuji, et al., 2014; Zeilmaker et al., 2011; Ryan, 2008), perfluorooctanoic acid (Chen et al., 2013;) and organochlorines (Vested et al., 2014; Eskenazi, et al., 2008). Of the many health effects associated with in utero exposures, developmental neurotoxicity appears to result from many environmental pollutants and this brief review indicates there may exist sufficient data for a number of environmental pollutants to focus on the decrements in IQ. However, based upon the initial literature search other endpoints may be selected to compare across environmental pollutants. Current human health assessments for many of the environmental pollutants identified here have yet to fully evaluate effects associated with in utero exposures. A focused effort on specific health effects (i.e., developmental neurotoxicity) across a group of compounds may provide insight and methodologies for future risk assessments. The Work Assignment Manager (WAM) and other EPA internal reviewers will provide technical direction as necessary.

In conducting the literature review, subsequent analyses, and documents characterizing the state of the science and analyses, the Contractor shall follow, as applicable, the following EPA guidance documents:

- A Review of the Reference Dose and Reference Concentration Processes (U.S. EPA, 2002)
- Guidelines for Neurotoxicity Risk Assessment (U.S. EPA, 1998)

- Guidelines for Reproductive Toxicity Risk Assessment (U.S. EPA, 1996)
- Guidelines for Developmental Toxicity Risk Assessment (U.S. EPA, 1991)
- Guidelines for Mutagenicity Risk Assessment (U.S. EPA, 1986)
- Methods for Derivation of Inhalation Reference Concentrations and Application of Inhalation Dosimetry (U.S. EPA, 1994)
- Recommendations for and Documentation of Biological Values for Use in Risk Assessment (U.S. EPA, 1988)
- Guidelines for the Health Risk Assessment of Chemical Mixtures (U.S. EPA, 1986)
- Supplementary Guidance for Conducting Health Risk Assessment of Chemical Mixtures (U.S. EPA, 2000)
- A Framework for Assessing Health Risks of Environmental Exposures to Children (U.S. EPA, 2006)

III. STATEMENT OF WORK

A. Objective

The objective of this Work Assignment (WA) is to provide technical support for the development of analyses and documents characterizing the state of the science on health effects observed in human populations resulting from in utero exposures to environmental pollutants. Specific requirements for the proposed work are provided below and in guidance documents referenced in this Performance Work Statement (PWS).

B. Specific Requirements

The use of "redline" versions of the documents shall be employed throughout the process. All documents shall be technically edited for format and grammar before being submitted to the EPA Work Assignment Manager (WAM).

Task 1: Establish Communication

Within 3 days of start date of this WA, the Contractor shall schedule a conference call (not to exceed 1 hour) with the WAM and appropriate contractor staff to clarify outstanding questions and confirm the schedule and specific tasks.

Task 2: Work Plan, Staffing Plan, and Quality Assurance Project Plan (QAPP)

The Contractor shall prepare a Technical Work Plan describing how the work outlined in this Performance Work Statement will be performed, including deliverables, a schedule, budget, and level of effort. The Contractor shall also prepare a Staffing Plan, which shall be submitted as part of the Work Plan that shows assigned personnel by task and the qualifications of the proposed personnel. The Contractor shall provide expertise in the basic science areas of toxicology, pharmacology, physiology, chemistry, epidemiology, human health risk assessment, and statistics. A working knowledge of risk assessment methodology and EPA risk assessment guidelines is required.

The Contractor shall develop a QAPP for approval by the WAM and Quality Assurance Manager. The Contractor must address in the QAPP how they are going to consider the use of secondary data to carry out this task. Secondary data are defined as environmental or health data that were developed for a different purpose. This includes data used from citations found in the literature. See these documents: "EPA Manual C/0 2105-P-01-0: EPA Quality Manual for Environmental Programs (QAPP)"; "EPA Requirements for Quality Assurance

Project Plans (QA/R-5)"; and "Appendix A. Guidance on Quality Assurance Project Plans for Secondary Research Data."

The QAPP shall be submitted simultaneously with the Work Plan for approval. The Contractor shall not perform any work on subsequent tasks under this WA until the Work Plan and QAPP are reviewed and approved.

Task 3: Literature search for identification of human epidemiological literature of health effects due to in utero exposure to environmental pollutants

Prior to initiation of Task 3, a broad literature and internet search should be conducted to identify projects and/or reports describing similar efforts to Tasks 3-6 of this work assignment. The findings of this search should be provided to the WAM for concurrence to conduct the remaining efforts described in Task 3. The objective of this task is conduct complete literature searches to identify human epidemiological data and toxicological data (i.e., animal studies) that have observed human health effects in later life due to exposure to environmental pollutants in utero. Based upon the environmental pollutants there may be a range of available data. At this point, literature searches shall be inclusive of cancer and non-cancer effects associated with in utero exposures to environmental pollutants. The literature search strategy shall be documented and characterize the numerical results of the search. Based upon this literature search, data should be summarized in Hazard ID Summary tables (i.e., similar to tables developed for the inorganic arsenic human health risk assessment) for review and subsequent direction of this effort (i.e., selection of health effect endpoints to further characterize). When necessary, EPA will provide technical guidance to clarify specific requirements of the task.

Specific requirements of this task:

3.1 Literature Search and Hazard ID Summary Tables and Summary Report: The Contractor shall assist EPA in preparing revised versions of literature search and Hazard ID Summary tables based upon reviewer comments. A summary report will be drafted to characterize the available hazard information (human and animal) for environmental pollutants identified in the literature search and to delineate a decision for the selection of health effect(s) / endpoint(s) for further analyses in this PWS. Comparability of data across relevant studies for the selected endpoints should be a key consideration in the selection of the health effect(s) / endpoint(s). Based upon the literature search results, PECO statements will be developed to guide subsequent analyses. Reviewers may include, but are not limited to, internal Agency and interagency participants.

Deliverables:
Literature search product and documentation
Hazard ID Summary tables
Summary report to document the available hazard information for identified chemicals, selection of health effects and develop PECO (population exposure comparison outcome) statement(s) for further analysis (based upon technical direction)

Task 4: Systematic Review Data Extraction, Development of Summary Figures

The objective of this task is to generate the data needed to conduct the analyses needed for a systematic review of the available literature for the selected endpoint(s) to determine the most appropriate studies for inclusion in the analysis. This task will be highly dependent upon the available literature and selection of endpoint(s) / health effects to characterize across a group of environmental pollutants from Task 3. The systematic review

will be conducted on multiple endpoints / health effects identified in Task 3, but only endpoint(s) with sufficient data to support a robust analysis. Technical direction will be provided by the WAM as to selection of endpoints and priority for conducting the systematic review. The systematic review will be guided by the PECO statements developed in Task 3 and be limited in scope. The protocol for the systematic review (including risk of bias) will be documented prior to evaluating studies. Although protocol development is outlined in Task 4, there will exist overlap with Task 3 which will require partial development of the protocols for completion of Task 3.

EPA will provide technical direction to finalize and define specific health endpoints for analysis. Technical direction will include but not be limited to providing literature search terms for consideration and refinement of the final endpoint definition. Based on the endpoints identified by EPA (i.e. hypospadias, asthma, cognitive effects, and birth outcomes) the Contractor shall screen and characterize the studies identified through the application of the literature search methodology in order complete and/or identify the set of studies to be included in the analysis. At a minimum, eligible studies shall evaluate NHANES chemicals, use a biomarker in their exposure assessments and examine in utero exposures. Lists of additional informative studies may be compiled as needed.

The Contractor shall extract relevant data from the identified set of studies for each of the endpoint groupings. Data shall include but not be limited to the following:

(1) Measure of effect or association;
(2) Chemical
(3) Biomarker
(4) Outcome
(5) Covariates considered (e.g. age, sex)
(6) Dose-response analysis (Yes/No)
(7) Other study details (e.g. population, comparison, study design, outcome ascertainment)

The Contractor shall assist EPA in efforts to standardize or transform data so that it can be plotted and over-layed with NHANES exposure distribution data (see Task 5).

Specific requirements of this task:

4.1 Systematic Review Methods Report: The Contractor shall develop a report summarizing the methods applied in the project overall and in the hypospadias pilot project.

4.2 Revise report: In Consultation with EPA, the Contractor shall revise and frame findings from the report so that they is suitable for publication in a peer-reviewed journal. The Contractor shall provide written outline(s) to the WAM for review prior to writing the report. The Contractor shall participate in telephone meetings as needed with EPA staff.

Deliverables:
Systematic Review Methods Report
Summary report of systematic review of selected studies (i.e. hypospadias)

Task 5: Efforts related Exposure Characterization

The objective of this task is to characterize exposure to the identified environmental pollutants using existing public databases. The National Health and Nutrition Examination Survey (NHANES) routinely collects biomarkers of exposure (e.g., blood and urine levels) for well- known environmental pollutants. For the environmental pollutants identified in Task 3, for which there is sufficient epidemiological data to suggest a potential human health hazards, NHANES and other publicly available databases will be searched to identify biomarkers of exposure. Based upon the available data the goal of this task will be to characterize the distribution of exposure to women of reproductive age, however this task will be limited by the available data. The approach and boundaries for identification, data retrieval, and exposure characterization will be dependent upon the environmental pollutants identified in Task 3. When necessary, EPA will provide technical guidance to clarify specific requirements of the task.

Specific requirements of this task:

5.1 Exposure Characterization: The Contractor shall assist EPA in drafting documents to characterize the exposure profile within United States populations and the retrieval of exposure information from publicly available databases

Deliverables:
General exposure profiles for US populations for each environmental pollutant (estimated 10)
Exposure characterization based upon exposure biomarkers from publicly available databases for women of reproductive age

Task 6: Efforts related to evaluation of toxicological data and ~~development of~~ existing Adverse Outcome Pathways (AOPs) available in the peer-reviewed literature

The objective of this task is to assist EPA in evaluating the available mechanistic information for the endpoint(s) selected in Task 3. Based upon the endpoint selected in Task 3, the contractor shall conduct a complete literature search for toxicological and mechanistic information for the selected endpoint(s). The available information should be arranged by components of AOP analysis (i.e., molecular initiating event, etc.). Based upon the endpoint(s) selected a review of available proposed AOPs or modes of action (MOA) should also be evaluated. Based upon the available information the WAM will provide technical direction as to the feasibility of developing an AOP for the selected endpoints.

Specific requirements of this task:

6.1 Evaluation and Analyses: The contractor shall develop a summary report characterizing the available toxicological and mechanistic information available for development of AOPs for the selected endpoint. Further analyses may be required to document and develop an AOP analyses.

Deliverable:
Summary report of available toxicological and mechanistic information
Review of available AOP hypotheses

Task 7: Characterization of Risk Estimation Methodology and Potential Future Directions

The objective of this task is to assist EPA in characterize the available / current approaches for hazard identification and dose-response analysis of developmental, reproductive, and health effects occurring later in life due to in utero exposures. A report shall be developed to characterize the current approaches by EPA and other risk assessment organizations. Additionally, considering the unique data sets available for in utero exposure, reproductive, and developmental studies the report will explore the development of new risk assessment methodological approaches to adequately account for health effects reported within the study types listed in this task. The advantages and disadvantages of current and proposed future approaches shall be characterized in this report.

Specific requirements of this task:

7.1 Risk assessment approaches: The contractor shall develop a summary report characterizing current and possible future approaches for hazard identification and dose-response analysis for developmental, reproductive, and health effects resulting from in utero exposure.

Deliverable:
Summary report for current and future risk assessment methodologies for specific types of studies

IV. ANTICIPATED DELIVERABLES

All products by the Contractor must be of high quality, written in a clear concise style, with a logical organization and presentation. Deliverables shall be provided to EPA in electronic formats compatible with EPA-supported software (e.g., Excel spreadsheets, Word documents, BMDS accessory files [*.(d), *.out, *opt, *.ssn]).

V. DELIVERABLES AND SCHEDULE

Task 1. Initial Conference Call	3 days after award of Work Assignment
Task 2. Staffing Plan, and QAPP	15 days after award
Task 3. Literature Search for Epi Literature from In Utero Exposures	
Task 3.1 – Literature Search and Hazard ID	
• Literature Search Product and Documentation	June 30, 2016
Task 4. Systematic Review	
Task 4.1 – Systematic Review and Dose-Response Analyses	
• Methods Report (including hypospadias pilot)	June 30, 2016
Asthma o Literature Search Result Summary o List of Studies and Chemicals o Data Extraction and Standardization o Summary Plots	TBD
Cognitive Effects o Literature Search Result Summary o List of Studies and Chemicals o Data Extraction and Standardization o Summary Plots	TBD
Birth Outcomes o Literature Search Result Summary o List of Studies and Chemicals o Data Extraction and Standardization o Summary Plots	TBD
Task 5. Efforts Related to Exposure Characterization	
Task 5.1 – Exposure Characterization	
• General Exposure Profiles for Selected Pollutants	June 30, 2016
• Exposure Characterization Publicly Available Biomarker Data	June 30, 2016
Task 6. Efforts related to AOPs	
Task 6.1 – AOP Evaluation and Analyses	
• Summary Report of Available Toxicological and Mechanistic Info for Selected Endpoint(s)	4 weeks from completion of Task 4
Task 7. **Characterization of Risk Estimation Methodology and Potential Future Directions**	
Task 7.1 – Risk assessment approaches	
Summary Report of Available Mechanistic Info for Selected Endpoint(s)	June 30, 2016
• Summary report for current and future risk assessment methodologies for specific types of studies	

Note: All days are calendar days.

VI. MANAGEMENT CONTROLS

1. All deliverables shall be reviewed for conformance to the requirements of this work assignment before being approved as final.

2. The contractor shall comply with other applicable requirements for final work assignment reports stipulated in contract.

VII. NOTICE REGARDING GUIDANCE PROVIDED UNDER THIS PROJECT

Guidance is strictly limited to technical and analytical support. The contractor shall not engage in activities of an inherent governmental nature such as the following:

(1) Formulation of Agency policy
(2) Selection of Agency priorities
(3) Development of Agency regulations

Should the contractor receive any instruction from an EPA staff person that the contractor ascertains to fall into any of these categories or goes beyond the scope of the contract or work assignment, the contractor shall immediately contact the PO , WAM or CO

VIII. SPECIAL CONDITIONS AND ASSUMPTIONS

The contractor shall hold a conference call with the EPA WAM at the initiation of the work assignment, and shall provide a bi-weekly update to the WAM by telephone for the duration of the work assignment, in addition to the standard reporting requirements of the contract.

IX. EPA CONTACT INFORMATION

Copies of all correspondence pertaining to the performance of this work assignment shall be sent to the PO.

Work Assignment Managers (WAMs):

Andrew Hotchkiss, PhD
919-541-4164
Hotchkiss.Andrew@epamail.epa.gov

Ellen Kirrane, PhD
919-541-1340
Kirrane.Ellen@epamail.epa.gov

Appendix A

Quality Assurance Instructions for Contractors Citing Secondary Data

Section 515 of the Treasury and General Government Appropriations Act for fiscal year 2001 directed the Office of Management and Budget (OMB) to issue guidelines to all Federal agencies to ensure and maximize the quality, objectivity, utility, and integrity of the information they disseminate. This law and the OMB guidance subsequently issued in 67 FR 8452 (02/22/02) underscore the need for EPA/NCEA to assess the quality and credibility of the secondary research information cited in its assessment documents.

Secondary research information is defined as information that was originally produced for one purpose but is now being recompiled or reassessed for a different purpose. Secondary research information usually originates from such primary sources as journal articles, books, government and industry reports, databases, and models. The set of processes that follows serves as a guide to evaluate the strength of secondary data gathered from these primary sources.

The Contractors must list the sources for the references cited in his/her document chapters or sections. The source list will include but not be limited to the names of any commercially available or local databases searched by computer or by hand, the search terms and search strategy used, and the time period of the search. List any print sources like books or journal articles which provided references. List any sources of raw data.

After fully reporting all of the reference sources, identify the most relevant information or key studies among the references you cite and critically evaluate them. Key studies are those most crucial or pivotal to answer the research questions for the project. The key study may have positive or negative results and may even be all that is currently available on the research topic, but the key study is integral to any discussion of the topic. Sometimes, the key study is not recognizable until all of the literature is gathered and evaluated. Key studies should exhibit at least most of the general attributes defined below:

FOCUS: the work not only addresses the area of inquiry under consideration but also contributes to its understanding;
VERIFY: the work is consistent with accepted knowledge in the field or, if not, the new or varying information is documented within the work; the work fits within the context of the literature and is intellectually honest and authentic;
INTEGRITY: Is the work structurally sound? In a piece of research, is the design or research rationale logical and appropriate?
RIGOR: the work is important, meaningful, and non-trivial relative to the field and exhibits sufficient depth of intellect rather than superficial or simplistic reasoning;
UTILITY: the work is useful and professionally relevant; it makes a contribution to the field in terms of the practitioners' understanding or decision-making on the topic.
CLARITY: Is it written clearly and appropriately for the nature of the study?

Use the check list on the following page to evaluate the key studies.

DATA CHECKLIST FOR EVALUATING A STUDY

1.) Bibliographic identification of the study.

Study Identifiers:
Author(s):
Title:
Study Citation:
Storage location (e.g., library, facility archive, personal archive):

2.) Why is the study key to the particular project? (For example, is the study an example of new research or confirmation of previous work? Is the study's population larger or followed for a longer period of time than before, is the methodology better than other studies or corrective of problems in previous studies, or do the results provide new insight into the problem?)

3.) Summarize the study structure and methodology. What sampling techniques and statistical tests are used?

4.) Potential problem areas in the study; consider: study design, factors occurring within and outside of the study which may affect its validity, sampling errors, and any other perceived weaknesses.

5.) Do any data used from sources outside of the study seem reliable and generally free of measurement error? Discuss and give examples.

6.) Evaluate the study in terms of the appropriateness of the analytical methodology. In responding, consider the following questions:

Are research questions clearly stated; dependent and independent variables clearly defined?

Do the authors explain the type of data obtained from measures of the variables?

Are statistical methods adequately described; are they justified?

Is a source provided for the any statistical software used to analyze the data?

Is the purpose of the analysis clear?

Are any scoring systems described?

Are potential confounders adequately controlled for in the analysis?

Are analytic specifications of the variables consistent with the evaluation questions or hypotheses under study?

Is the unit of analysis specified clearly?

If statistical tests are used to determine comparability or difference, are p values provided; is the practical significance of these findings, as contrasted with the statistical significance, discussed?

7.) Evaluate the study's results. Consider the following questions:

Are study questions (objectives, hypotheses) clear?

Are all study questions answered?

Are negative findings presented?

Are missing data explained?

Are text and tables, figures, and graphs consistent?

8.) Evaluate the study's conclusions. Consider the following questions:

Are the conclusions based on the study's data in that findings are applied only to the sample that was included in the research?

When the authors compare their findings with those from another study, do the authors demonstrate the similarity of the two studies?

Does the author discuss limitations of design, sampling, data collection, etc.?

To what extent do the limitations affect one's confidence in the conclusions?

9.) How strong is the study, overall; relative to other similar studies? Do its weaknesses jeopardize its being a key study, or is it usable despite the reservations?

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 3-47

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-14-001	11/01/2013 To 10/31/2017	TOXCAST QC DOC
	Base Option Period Number 3	

Contractor: ICF INCORPORATED, L.L.C.

Specify Section and paragraph of Contract SOW:

Purpose:
- [X] Work Assignment
- [ ] Work Assignment Amendment
- [ ] Work Plan Approval
- [ ] Work Assignment Close-Out
- [ ] Incremental Funding

Period of Performance: From 11/01/2016 To 10/31/2017

Comments:

☐ Superfund — Accounting and Appropriations Data — [X] Non-Superfund

SFO (*Max 2*): ☐

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

	Cost/Fee	LOE
Contract Period: 11/01/2013 To 10/31/2017		
This Action:		
Total:		

Work Plan / Cost Estimate Approvals

	Cost/Fee	LOE
Contractor WP Dated:		
Cumulative Approved:		

Work Assignment Manager Name: Sandra Roberts (Signature) (Date)	Branch/Mail Code: Phone Number: 919-541-3850 FAX Number:
Project Officer Name: Melissa Revely-Wilson (Signature) (Date)	Branch/Mail Code: Phone Number: 919-541-0207 FAX Number:
Other Agency Official Name: (Signature) (Date)	Branch/Mail Code: Phone Number: FAX Number:
Contracting Official Name: William Yates (Signature) (Date)	Branch/Mail Code: Phone Number: 513-487-2055 FAX Number:

PERFORMANCE WORK STATEMENT
CONTRACT NO. EP-C-14-001
WA 3-47

TITLE: TECHNICAL SUPPORT FOR TOXCAST QC DOCUMENTATION

PERIOD OF PERFORMANCE: CO approval through 10/31/2017

I. PURPOSE

The purpose of this modification is to develop a report, a plan, and a user's guide with accompanying information from the independent audit of the ToxCast database computer code for consistency and accuracy. This work falls under Heading III - Specific Areas of Work, Section C (Risk Assessment Data Bases and Computer Tools, paragraph 1) and Section F (Information Management). Also relevant to this modification is Heading IV- Product Quality, Section B (Quality Assurance/Quality Control Requirements) as it relates to ensuring that data generated are "of the type and quality needed and expected for their intended use."

II. BACKGROUND

The National Center for Computational Toxicology (NCCT) of the U.S. Environmental Protection Agency's (EPA's) Office of Research and Development (ORD) is developing innovative scientific approaches for screening thousands of chemicals for biological activity and exposure in an effort to predict potential health effects. EPA's Toxicity Forecaster (ToxCast) research effort generates data and predictive models on thousands of chemicals of interest to the EPA.

ToxCast uses high-throughput screening methods and computational toxicology approaches to rank and prioritize chemicals. In fact, EPA's Endocrine Disruption Screening Program (EDSP) is using ToxCast data to rank and prioritize chemicals. ToxCast has data on over 8,000 chemicals from a broad range of sources including industrial and consumer products, food additives, and potentially "green" chemicals that could be safer alternatives to existing chemicals. As part of EPA's commitment to gather and share its chemical data in open and transparent ways, all ToxCast data, information, code, etc is publicly available.

The data used to develop the methods and models goes through a quality review process called the ToxCast data analysis pipeline. Information resulting from the data analysis pipeline process (raw and processed data, flags, model parameters, etc.) are stored in a MySQL relational database called InvitroDB. In addition, all other information and data resulting from screening chemicals for potential health effects are publicly available on the ToxCast data download website (https://www.epa.gov/chemical-research/toxicity-forecaster-toxcasttm-data). NCCT has also developed the ToxCast Dashboard (https://actor.epa.gov/dashboard/) which is an interactive

online tool for visualizing and using the chemical screening data resulting from the ToxCast data analysis pipeline.

There are two critical topics related to regulatory use and public acceptance of using this new data to evaluate chemicals for potential health effects; 1) Data is viewed as scientifically accurate and 2) Users understand how to use and interpret the data to inform decisions made about the health effects of chemicals. To provide evidence of scientific accuracy, ICF performed an independent audit of all the information and data resulting from ToxCast. Following the independent review, ICF developed a summary of their findings which describes specific areas for improvement. A key finding was the need to develop tools to help users interpret ToxCast data and use the information to inform decisions made about potential health effects.

The next step is to address the second critical topic by developing tools and resources to help users understand how to use and interpret the information resulting from the analysis pipeline. To take this next step, the proposed project will use the summary of the ICF audit findings to develop a User's Guide and accompanying graphics to visually show all of the available data and information as well as how it all works together to help evaluate chemicals.

III. STATEMENT OF WORK

Task 1: Using the audit findings, provide a detailed report outlining recommendations for improving ToxCast data documentation (e.g., R documentation, ToxCast data analysis pipeline overview, ToxCast assay summary, readme, and standard operating procedures files) and to develop a plan for adding for new information to help users interpret the ToxCast information.

Step 1: Using ICF International's (ICF's) testing and audit of the installation of the ToxCast Pipeline (tcpl) R package using its vignette dated May 17, 2016 and other documentation available on U.S. EPA's ToxCast website, the contractor will create a detailed report outlining recommendations for improving ToxCast data, information and related documentation (i.e., tcpl-related documentation).

Step 2: Using the detailed report resulting from Step 1, the contractor shall provide a detailed plan to help users interpret the ToxCast information. The plan will include strategies such as combining information, expanding documentation, adding new information and suggestions for how to display the information on EPA's ToxCast website. Types of information that may be described in the plan are documentation of chemical and sample acquisition, handling and analytical quality control, summary of input data, use of tcpl, summaries of output files, and use of existing web-based dashboards for data retrieval and use. The contractor shall provide this deliverable to the EPA for review, and revision as needed, prior to beginning work on Task 2.

Task 2: Provide a ToxCast Data User's Guide and Accompanying Graphics and Information

Step 1: Using the EPA approved plan from Task 2, the contractor shall develop a ToxCast Data User's Guide and accompanying graphics and information to help users interpret the data and use information to make decisions about how chemicals effect health. The User's Guide will describe how to use existing documentation, data (chemical and high-throughput screening data), R-package, MySQL database (with revisions as needed) to provide an accurate description of the entire workflow in ToxCast, from chemical procurement to data output and use in dashboards. The User's Guide will also describe documentation of the processes and suggestions for fitting all of the data/information together for use. The deliverable shall be a Word and PDF document with: a title page, a Table of Contents, Executive Summary, Introduction, chapters specific to documentation, chapters specific to fitting the pieces together for use, visuals that show how all of the pieces fit together, and any other discrete aspects of the workflow, a summary, Internet links, and an index of key words. The disparate sources of documentation will require normalization of language and format.
Step 2: Add a Frequently Asked Questions Document and a Master Dictionary. The Master Dictionary will be created by compiling information from the previously created data dictionaries, and new resources. The dictionary will also provide definitions of the assays.

IV. SUMMARY TIME TABLE.

Task	Deliverable	Time frame
1	Monthly summary of documentation progress, or communication for clarification as necessary	Monthly
2	Monthly summary of documentation progress, or communication for clarification as necessary	Monthly

1. The contractor shall be responsible for obtaining a conflict of interest certification for any subcontractor services.
2. All deliverables shall be in conformance with the requirements of the work assignment before such deliverables are approved as final. Electronic copy of all deliverable shall be sent to the EPA WA COR.
3. The contractor shall comply with other applicable requirements for final work assignment reports as stipulated in the Contractual Agreement.
4. The contractor shall prepare all deliverables in accordance with the Quality Management Plan for the contract.

V. MANAGEMENT CONTROLS

1. All deliverables shall be reviewed for conformance to the requirements of this work assignment before being approved as final.
2. The contractor shall comply with other applicable requirements for final work assignments reports stipulated in contract.

VI. NOTICE REGARDING GUIDANCE PROVIDED UNDER THIS TASK ORDER.

Guidance is strictly limited to technical and analytical support. The contractor shall not engage in

activities of an inherent governmental nature such as the following:

1. Formulation of Agency policy
2. Selection of Agency priorities
3. Development of Agency regulations

If the contractor receives any instructions from an EPA staff person that the contractor ascertains to fall into any of these categories or goes beyond the scope of the contract or work assignment, the contractor shall immediately notify the WA COR. The contractor shall also ensure that work under this Work Assignment does not contain any apparent or real personal or organizational conflict of interest. The contractor shall certify that no conflicts exist at the time the proposal is submitted to the EPA.

VII. EPA CONTACT INFORMATION.

Copies of all correspondence pertaining to the performance of this work assignment shall be sent electronically to the Work Assignment Contracting Officer's Representative (WA COR).

WA COR	**Alternate WA COR**
Matthew Martin National Center for Computational Toxicology Office of Research and Development U.S. Environmental Protection Agency 109 T.W. Alexander Dr. (B205-01) RTP, NC 27711 Telephone #: (919) 541-4101 FAX #: (919) 541-1194 Email: martin.matt@epa.gov	Sandra Roberts National Center for Environmental Assessment Office of Research and Development U.S. Environmental Protection Agency 109 T.W. Alexander Dr. (B205-01) RTP, NC 27711 Telephone #: (919) 541-3850 FAX #: (919) 541-1194 Email: roberts.sandra@epa.gov

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 3-47

☐ Other ☒ Amendment Number: 000001

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-14-001	11/01/2013 To 10/31/2017 Base Option Period Number 3	

Contractor: ICF INCORPORATED, L.L.C.

Specify Section and paragraph of Contract SOW:

Purpose:
- ☐ Work Assignment
- ☒ Work Assignment Amendment
- ☐ Work Plan Approval
- ☐ Work Assignment Close-Out
- ☐ Incremental Funding

Period of Performance: From 11/01/2016 To 10/31/2017

Comments:
Remove Matthew Martin as Alt. COR - left agency. All other terms and conditions remain unchanged.

☐ Superfund — Accounting and Appropriations Data — ☒ Non-Superfund

SFO (*Max 2*) ☐

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

Contract Period: 11/01/2013 To 10/31/2017 — Cost/Fee: — LOE:

This Action:

Total:

Work Plan / Cost Estimate Approvals

Contractor WP Dated: — Cost/Fee — LOE:

Cumulative Approved: — Cost/Fee — LOE:

Work Assignment Manager Name: Sandra Roberts (Signature) (Date)	Branch/Mail Code: Phone Number: 919-541-3850 FAX Number:
Project Officer Name: Melissa Revely-Wilson (Signature) (Date)	Branch/Mail Code: Phone Number: 919-541-0207 FAX Number:
Other Agency Official Name (Signature) (Date)	Branch/Mail Code: Phone Number: FAX Number:
Contracting Official Name: William Yates (Signature) (Date)	Branch/Mail Code: Phone Number: 513-487-2055 FAX Number:

PERFORMANCE WORK Statement
Contract EP-C-14-001
Work Assignment no. 3-48

.....

Title: **NCEA-HERO-DRAGON Interface & NCEA-HERO Support**

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SOW Section & Paragraph:
Section IIIC: (Risk Assessment Databases and Computer Tools); Paragraph 1

Note: This work assignment is a follow-on from work performed in the Year 2 Option Period under Work Assignment #2-48. The work continues all three Tasks (Task 1 through Task 3) during this Year 3 Option Period under Work Assignment 3-48.

Period of Performance: CO Approval to October 31, 2017

I. Purpose

The purpose of this work assignment is to provide services to the U.S. Environmental Protection Agency's (hereinafter EPA or Agency) in the Office of Research and Development (ORD), in the National Center for Environmental Assessment (NCEA). Specifically, to provide services to support the NCEA Health and Environmental Research Online (HERO) database system, which is a tool used in developing Human Health Science Assessments and other NCEA documents.

II. Background

HERO is U.S. EPA National Center for Environmental Assessment (NCEA) application database system containing bibliographic references used in assessment development process. HERO currently includes nearly 3 million bibliographic references; ~80% are articles from peer-reviewed scientific research journals. There are several modules and tools within the NCEA HERO database system (e.g., LitSearch, Literature Import tools, LitBrowser tools [includes Project Pages, Tagging, LitFlow diagrams, Generation of Project-specific EndNote Libraries, and LitCiter], LitScreener, LitExtractor, LitReporter, etc.).

III. Statement of Work

A. Objective

The contractor shall perform various tasks for NCEA in support of the various projects and modules in HERO. The WAM, Connie Meacham, and the Alt-WAM, Ryan Jones, will give technical direction on the support tasks.

The tasks involve:

- Continuing to develop a HERO-DRAGON interface (web services API), and a series of other (intermediary) methods of electronic transfer of information collected for NCEA in the ICF DRAGON tool (i.e., literature screening data, modeling data, extracted data, and formatted DRAGON output) into HERO.

- Data cleaning and quality control of information on at least 10 different HERO Project Pages and any associated LitFlow Diagrams associated with various programs within NCEA (such as ISAs, IRIS Toxicological Reviews, PPRTVs, and Other high-profile projects).

The WAM (or Alt-WAM) will provide prompt feedback to the contractor on the acceptability and performance of the tasks.

B. Specific Requirements

Task 1: Submit Work Plan for WA 3-48, to reflect the continuation of WA 2-48.

Task 2: Continue to develop a HERO-DRAGON interface (web services API), and a series of other (intermediary) methods of electronic transfer of modeling data, screening data, and extracted data from DRAGON into HERO. Additional alternate methods of phased electronic data transfer will be necessary to move this task forward toward the completion of the API. Once the API is in place, all the data collected for NCEA into the DRAGON MS Access databases, the DRAGON MySQL database, and into the DRAGON OnLine tool shall be automatically exported by ICF to EPA (and automatically imported into the NCEA HERO database system) on a regular ongoing basis.

Skills needed: Understanding of web services API (Application Programming Interface), Microsoft Office (MS) Access Databases, MS Excel Spreadsheets, xml format, JSON Objects, JAVA, Word Tables, MySQL databases, NoSQL databases, and DRAGON processes (literature screening, DRAGONScreen, data extraction / fact extraction) and DRAGON queries and output formats.

Task 3: Data cleaning and quality control of information on various HERO Project Pages and LitFlow diagrams.

EPA will provide the EPA Portal accounts and HERO tools and permissions as necessary.

Skills needed: Attention to detail, understanding of bibliographic reference data, a thorough understanding of HERO applications and EPA user environment, technical writing skills, an understanding of the assessment development process.

The WAM (or Alt-WAM) will assign the projects for which the bibliographic references shall be checked for completeness and accuracy. Each project shall be checked for appropriateness of the "tag tree" associated with the project on the Project Page and the LitFlow diagram. This "tag tree" checking may involve the EPA chemical (project expert/assessment manager) manager of the project as well as the WAM and/or Alt-WAM. The contractors shall enter corrections directly in the HERO database using the HERO web interface or send importable data to the HERO Technical Lead, Ryan Jones.

IV. Deliverables

All deliverables will be electronic.

All technical directions will be given via email.

Email and weekly teleconferences will be used to communicate with the contractor.

Notice Regarding Guidance Provided under this Project

Guidance is strictly limited to technical and analytical support. The contractor shall not engage in activities of an inherent governmental nature such as the following:

(1) Formulation of Agency policy
(2) Selection of Agency priorities
(3) Development of Agency regulations

Should the contractor receive any instruction from an EPA staff person that the contractor ascertains to fall into any of these categories or goes beyond the scope of the contract or work assignment, the contractor shall immediately contact the PO, WAM, and Alt-WAM.

V. Special Conditions and Assumptions

The contractor shall hold a conference call with the EPA WAM at the initiation of the work assignment.

Periodic meetings (generally once every week, or once every 2 weeks if there are scheduling conflicts) between the EPA WAM (and possibly the Alt-WAM and HERO Technical Lead) and contractor staff shall be necessary to discuss questions that may arise during performance or completion of this work assignment. At the EPA WAM's discretion, these meetings may occur via teleconference or webinar. The contractor shall document these meetings and submit copies of this documentation to the EPA WAM.

Travel: No Travel is expected to occur during the course of this work assignment.

Green Meetings: No in-person meetings are expected to occur during the course of this work assignment.

- For ICF Work Assignments from NCEA that have "Data Extraction" or "Evidence Tables" or "Systematic Review" or "DRAGON-SCREEN" or "DRAGON" or "DRAGON-ONLINE" as part of the task(s) in the Work Assignment:
    - In addition to the deliverables in this Work Assignment, ICF shall export data extracted for EPA into the ICF extraction systems (such as DRAGON Tools) to the NCEA HERO Database System (either by an API* or machine readable data files [if the API* is not ready], which can be automatically imported into the NCEA HERO Database System)."
    - *Definition of API: Application Program Interface - - a software intermediary that allows computer applications or systems to automatically interact with each other to share data.

VI. EPA Contact Information

Copies of all correspondence pertaining to the performance of this work assignment shall be sent to the PO (Melissa Revely-Wilson; revely-wilson.melissa@epa.gov).

Work Assignment Manager (WAM)

Connie A. Meacham, M.S. (Biologist)
HERO Project Lead
U.S. EPA, NCEA-RTP
109 TW Alexander Drive, Mail Drop B243-01
Research Triangle Park, NC 27711
Telephone: (919) 541- 3908
Cell: (919) 369-8600
meacham.connie@epa.gov

Packages/Courier Address:
Connie Meacham
U.S. EPA MD B243-01
4930 Old Page Road
Durham, NC 27703

Alternative Work Assignment Manager (Alt-WAM)

Ryan Jones, M.S. (Information Specialist)
HERO Technical Lead
U.S. EPA, NCEA-RTP
109 TW Alexander Drive, Mail Drop B243-01
Research Triangle Park, NC 27711
Telephone: (919) 541- 9415
Fax: (919) 541- 5078
jones.ryan@epa.gov

Packages/Courier Address:
Ryan Jones
U.S. EPA MD B243-01
4930 Old Page Road
Durham, NC 27703

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 3-49

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-14-001	11/01/2013 To 10/31/2017 Base Option Period Number 3	Ethylene Oxide

Contractor	Specify Section and paragraph of Contract SOW
ICF INCORPORATED, L.L.C.	A.1,2,4 and B.1,2,5

Purpose:
- [X] Work Assignment
- [ ] Work Assignment Amendment
- [ ] Work Plan Approval
- [ ] Work Assignment Close-Out
- [ ] Incremental Funding

Period of Performance: From 11/06/2016 To 10/31/2017

Comments:

☐ Superfund — Accounting and Appropriations Data — [X] Non-Superfund

SFO (*Max 2*): ☐

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

	Cost/Fee:	LOE:
Contract Period: 11/01/2013 To 10/31/2017		
This Action:		
Total:		

Work Plan / Cost Estimate Approvals

	Cost/Fee	LOE:
Contractor WP Dated:		
Cumulative Approved:		

Work Assignment Manager Name: John Fox (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	703-347-8598
	FAX Number:	
Project Officer Name: Melissa Revely-Wilson (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	919-541-0207
	FAX Number:	
Other Agency Official Name (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	
	FAX Number:	
Contracting Official Name: William Yates (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	513-487-2055
	FAX Number:	

PERFORMANCE WORK STATEMENT
CONTRACT NO. EP-C-14-001
WA 3-49

TITLE: Ethylene Oxide - Epidemiology Modeling and Exposure Characterization

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Principal Section & Paragraph of SOW: A.1,2,4 and B.1,2,5

PERIOD OF PERFORMANCE: date of approval by CO – October 31, 2017

I. PURPOSE

This work assignment is a continuation of WA 2-49. Task 2 of WA 2-49 has been completed. Only Task 3 remains in WA 3-49. The purpose of the work assignment is to provide services to the U.S. Environmental Protection Agency's (EPA) National Center for Environmental Assessment (NCEA), Office of Research and Development (ORD), in the completion of a carcinogenicity assessment for Ethylene Oxide. Specifically, this work assignment will provide exposure-response modeling using NIOSH cohort study data, and characterizations of exposure levels estimated for jobs and locations pertinent to the cohort study.

II. BACKGROUND

EPA's Integrated Risk Information System (IRIS) is a human health assessment program that evaluates quantitative and qualitative risk information on effects that may result from exposure to environmental contaminants. When supported by available data, the database provides oral reference doses (RfDs) and inhalation reference concentrations (RfCs) for chronic non-cancer health effects, and oral slope factors and inhalation unit risks for carcinogenic effects. Government and private entities use IRIS to help characterize public health risks of chemical substances in a site-specific situation and thereby support risk management decisions designed to protect public health. IRIS contains chemical-specific summaries of qualitative and quantitative health information in support of two steps of the risk assessment process, i.e., hazard identification and dose-response evaluation. IRIS information includes the reference dose for non-cancer health effects resulting from oral exposure (the RfD), the reference concentration for non-cancer health effects resulting from inhalation exposure (the RfC), and the carcinogen assessment for both oral and inhalation exposures. Combined with specific situational exposure assessment information, the summary health hazard information in IRIS may be used as a source in evaluating potential public health risks from environmental contaminants.

III. SCOPE OF WORK: TASKS AND DELIVERABLES

Task 1: Work Plan and Quality Assurance Project Plan (QAPP)

The contractor shall prepare a Work Plan and a Quality Assurance Project Plan (QAPP). The Work Plan shall state that the QAPP will be observed during the conduct of this work assignment. The QAPP shall be submitted simultaneously with the work plan for approval. The contractor shall not perform any work under the other tasks of this Project until the contractor receives a signature page from EPA for the QAPP, showing approvals by the Work Assignment Manager, the contract Project Officer, and NCEA's QA official.

Deliverables: QAPP
Due Date: 15 days after issuance of this Performance Work Statement (PWS).

Task 2. Exposure-Response Modeling of NIOSH Mortality Cohort Study Data and Exposure Characterization THIS TASK HAS BEEN COMPLETED

~~Exposure-response modeling was conducted for the Ethylene Oxide ("EtO") assessment prior to SAB review. The SAB requested further analyses. These were addressed under WA 1-49. This task provides for a limited LOE of no more than 40 hours for revising or amending work done under WA 1-49, including:~~

- ~~a. exposure-response modeling of the lymphoid cancer mortality data in the NIOSH cohort study, including sensitivity analyses of various models and model features (such as knot choices, age-exposure interactions)~~
- ~~b. characterization of the exposure distributions in the cohort and their changes over time~~
- ~~c. analysis of selected characteristics of the cohort~~
- ~~d. consultation with EPA on working with the cohort study data and review of analyses that can be conducted by EPA staff~~
- ~~e. addressing specific SAB comments about the exposure-response modeling:~~
  - ~~i. discuss the extent to which the NIOSH study results are consistent with results from the Union Carbide Cohort study and the Mikoczy et al. (2011) study~~
  - ~~ii. put the extra lifetime risk in terms of the number of lymphoid cancers that are due to exposure to EtO in the cohort~~
- ~~f. examination and characterization of exposure levels in relation to jobs, locations and time~~

~~Deliverables: To be specified in written technical direction~~
~~Due Dates: To be specified in written technical direction~~

Task 3: Consultation with EPA staff and assistance with responses to SAB comments

This task provides for a limited quantity of assistance with explaining, and executing data analyses and writing or reviewing draft responses to the SAB comments. The Task is expected to require less than 40 hours.

a. consultation with EPA on working with the cohort study data and review of analyses that can be conducted by EPA staff
b. assistance in responding to SAB comments about the exposure-response modeling; review of selected responses

Deliverables: To be specified in written technical direction
Due Dates: To be specified in written technical direction

V. SCHEDULE OF DELIVERABLES

This schedule and the deliverables dates specified under each Task above may be changed using written Technical Direction.

Task	**Schedule** (all days are elapsed calendar days unless otherwise stated)
1. Work Plan and Quality Assurance Project Plan	15 days after receipt of this PWS
~~2. Exposure-Response Modeling of NIOSH Cohort Study Data and Exposure Characterization~~	~~To be specified in written technical direction~~ COMPLETED
3. Consultation with EPA staff and assistance with responses to SAB comments	To be specified in written technical direction

VI. NOTICE REGARDING GUIDANCE PROVIDED UNDER THIS PROJECT

Guidance is strictly limited to technical and analytical support. The contractor shall not engage in activities of an inherently governmental nature such as the following:

(1) Formulation of Agency policy
(2) Selection of Agency priorities
(3) Development of Agency regulations

Should the contractor receive any instruction from an EPA staff person that the contractor ascertains to fall into any of these categories or goes beyond the scope of the contract or work assignment, the contractor shall immediately contact the PO or WAM.

The contractor shall also ensure that work under this work assignment does not contain any apparent or real personal or organizational conflict of interest. The contractor shall certify that none exist at the time the proposal is submitted to EPA. The Contractor shall be responsible for obtaining a conflict of interest certification for any subcontractor services.

VII. SPECIAL CONDITIONS AND ASSUMPTIONS

The contractor shall provide regular updates on progress and any issues that need to be resolved to the WAM by telephone or by email. Any technical directions made during informal discussions shall be issued promptly by the EPA WAM in writing (to include email).

VIII. EPA CONTACTS

EPA Project Officer (PO)

Melissa Revely-Wilson, Acquisition Specialist
Office of Research and Development (8601-P)
Office of Administrative and Research Support
Extramural Management Division - Contracts Branch
Telephone: 703/347-8523 (AWL 540/891-6405) Fax: 703/347-8696
Revely-Wilson.Melissa@epa.gov

Mailing Address:
National Center for Environmental Assessment
Office of Research and Development (8623-P)
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Physical Address:
U.S. Environmental Protection Agency
Two Potomac Yard (North Building),
2733 S. Crystal Drive, Arlington, VA 22202

EPA Work Assignment Manager (WAM)

John Fox
703-347- 8598 (voice), 703-347-8690 (fax), email Fox.John@epa.gov
Mailing Address:
U.S. EPA, ORD/NCEA-Washington (Mail Code 8601 P)
1200 Pennsylvania Ave, NW, Washington, D.C. 20460

Courier Deliveries:
U.S.E.P.A. Office of Research and Development, National Center for Environmental Assessment
Two Potomac Yard North, 7th Floor N-7954, 2733 S. Crystal Drive, Arlington, VA 22202

Technical Advisor (Not a WAM/or COTR)
Jennifer Jinot (Assessment Manager for Ethylene Oxide; EPA Statistican)
703-347-8597 jinot.jennifer@epa.gov

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 3-50

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-14-001	11/01/2013 To 10/31/2017	Support of EPA-Eco-Box
	Base Option Period Number 3	

Contractor	Specify Section and paragraph of Contract SOW
ICF INCORPORATED, L.L.C.	CIII

Purpose:
- [X] Work Assignment
- [ ] Work Assignment Amendment
- [ ] Work Plan Approval
- [ ] Work Assignment Close-Out
- [ ] Incremental Funding

Period of Performance: From 11/01/2016 To 10/31/2017

Comments:

☐ Superfund — Accounting and Appropriations Data — [X] Non-Superfund

SFO (*Max 2*): ☐

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

	Cost/Fee:	LOE:
Contract Period: 11/01/2013 To 10/31/2017		
This Action:		
Total:		

Work Plan / Cost Estimate Approvals

	Cost/Fee	LOE:
Contractor WP Dated:		
Cumulative Approved:		

Work Assignment Manager Name: Linda Phillips (Signature) (Date)	Branch/Mail Code: Phone Number: 703-347-0366 FAX Number:
Project Officer Name: Melissa Revely-Wilson (Signature) (Date)	Branch/Mail Code: Phone Number: 919-541-0207 FAX Number:
Other Agency Official Name: (Signature) (Date)	Branch/Mail Code: Phone Number: FAX Number:
Contracting Official Name: William Yates (Signature) (Date)	Branch/Mail Code: Phone Number: 513-487-2055 FAX Number:

PERFORMANCE WORK STATEMENT
CONTRACT NO. EP-C-14-001
WA 3-50

TITLE: Technical Support for EPA-Eco-Box (a toolbox for ecological risk assessors)

Specify Section & Paragraph SOW: III.C.

PERIOD of PERFORMANCE: CO approval through 10/31/2017.

I. PURPOSE.

The purpose of this work assignment is to obtain technical support services to the US Environmental Protection Agency's (EPA), Office of Research and Development (ORD), National Center for Environmental Assessment (NCEA) for EPA-Eco-Box (a toolbox for ecological risk assessors).

II. BACKGROUND AND OBJECTIVES.

EPA's Office of Research and Development, National Center of Environmental Assessment (NCEA) is developing EPA-Eco-Box as a web-based compendium of tools used in ecological risk assessment. It will be comprised of a series of Tool Sets, each containing modules that address topics in ecological risk assessment. Each toolbox module will contain a description of the topic and links to ecological risk assessment resources that address that topic, including databases, models, guidance documents, and other relevant tools. A search interface will allow users to identify resources using keywords or topics. Technical assistance will be required for finalizing the development of EPA-Eco-Box that began under work assignment 1-50 and continued under work assignment 2-50 of this contract, and updating/revising the toolbox, as needed. This will include: finalizing Tool Set module content and Master Tool List, addressing comments received from EPA-Eco-Box reviewers, and assisting with modifications or revisions, as needed. Development of the website to house EPA-Eco-Box is not included in this work assignment.

III. STATEMENT OF WORK.

The contractor shall be responsible for completion of four tasks. A summary of each task is provided below, including the time frame during which the task shall be completed.

Task 1. The contractor shall establish communication, submit a work plan, and arrange for routine updates for the EPA Contracting Officer's Representative (COR).

The contractor shall schedule an initial conference call **within 1 week** after the receipt of the work assignment. The call shall include the COR and relevant members of the ICF team.

Deliverable 1: The contractor shall arrange a conference call with the COR, **within 1 week after the receipt of the work assignment.**

Task 2. The contractor shall assist in finalizing the content for EPA-Eco-Box Tool Sets and modules.

The contractor shall finalize content for EPA-Eco-Box. This shall include providing revisions to the text and tool lists for each of the modules, as needed. Finalization may also include additions or revisions to graphics, photo images, or other types of reference materials, as needed to convey concepts of ecological risk assessment, as described in relevant EPA guidance documents. The draft revised content for the each of the Tool Sets shall be submitted to the COR **within 2 weeks of receiving technical direction from the COR.** The contractor shall submit final content **within 2 weeks of receiving comments on the draft content from the COR.**

Deliverable 2a: The contractor shall submit draft revised Tool Set and module content **within 2 weeks after being notified by the COR that they should begin work.**

Deliverable 2b: The contractor shall submit final Tool Set and module content **within 2 weeks of receiving comments on the draft content from the COR.**

Task 3. The contractor shall finalize/revise the Master Tool List for EPA-Eco-Box.

The contractor began development of a Master Tool List for EPA-Eco-Box under work assignments 1-50 and 2-50 of this contract. Its purpose is to provide a comprehensive listing of all the tools included in the toolbox, and will be used to:

(1) populate tables within each of the Tool Set modules with tools relevant to that topic area; and
(2) allow the toolbox to be searched using key words.

This Master Tool List will need to be finalized before EPA-Eco-Box can be deployed. It may also need to revised, as needed, based on reviewer comments or to add new or revised tools that become available or are identified after EPA-Eco-Box's initial release. The contractor shall finalize or revise the Master Tool list for EPA-Eco-Box. The contractor shall provide a listing of all tools to be included in EPA-Eco-Box along with a brief description, URL, and relevant key words.

The contractor shall provide the necessary information to revise and update the Master Tool List, as needed, to incorporate any new tools that have been identified from comments on the Toolbox, to add tools based on the revision of existing content or to add new or revised tools. The contractor shall also provide the necessary information to correct broken links in the Toolbox after deployment. It is assumed that broken link checks will be conducted twice a year after release. The contractor shall also ensure that any new or updated tools have been appropriately assigned to the various Tool Sets, modules, and sub-modules (many of the tools will be applicable in more than one module or sub-module), and that accurate tool descriptions and key words are provided. A record of all revisions and correction of broken links shall be maintained in an Excel spreadsheet. The contractor shall submit all of the draft information necessary to revise and update the Master Tool List to the COR **within 2 weeks after of receiving a written request from the COR**. **Within 1 week after receiving comments from the COR**, the contractor shall submit the final information necessary to update the Master Tool List.

Deliverable 3a: The contractor shall submit to the COR draft information necessary to revise and update the Master Tool List **within 2 weeks of receiving a written request from the COR.**

Deliverable 3b: The contractor shall submit the final information necessary to update the Master Tool List to the COR **within 1 week after the receipt of the COR's comments on Deliverable 3a**.

Task 4. The contractor shall assist in addressing comments on EPA-Eco-Box.

The contractor shall assist EPA in reviewing any comments received on EPA-Eco-Box, and formulating plans for addressing these comments. **Within 1 week after receiving comments from the COR**, the contractor shall arrange a conference call with the COR to discuss the comments and the next steps for making revisions to the Toolbox. The contractor shall prepare and submit to the COR draft responses **within 2 weeks of the COR assigning issues or topic areas** that will need to be addressed. For the purpose of preparing the work plan and cost estimate for this work assignment, the contractor shall assume that there are 5 key issues to be addressed, and that any other comments will require only minor revisions. The list of comments and their resolution shall be maintained in order to track revisions made to the Toolbox. This list will include key issues as well as other minor corrections.

Deliverable 4a: The contractor shall arrange a conference call with the COR **within 1 week after the receiving comments from the COR**.

Deliverable 4b: The contractor shall prepare responses to the issues **within 2 weeks of being assigned by the COR**.

The contractor shall furnish electronic copies of (or internet links to) any references or other materials obtained in the preparation of the deliverables for this work assignment.

.IV. TIME TABLE.

Task	Deliverable	Time frame
1a	Establish communication via conference call	Within 1 week after receipt of work assignment
2a	Submit draft revised Tool Set content	Within 2 weeks of being assigned by COR
2b	Submit final Tool Set content	Within 2 weeks of receiving comments on outline from EPA COR
3a	Submit draft update to Master Tool List	Within 2 weeks of receiving written request from COR
3b	Submit final update to Master Tool List	Within 1 week of COR comments
4a	Arrange conference call	Within 1 week of receiving comments from COR
4b	Prepare comment responses	Within 2 weeks of being assigned by COR

1. The contractor shall be responsible for obtaining a conflict of interest certification for any subcontractor services.

2. All deliverables shall be in conformance with the requirements of the work assignment before such deliverables are approved as final. Electronic copy of all deliverable shall be sent to the EPA Project Officer (PO).

3. The contractor shall comply with other applicable requirements for final work assignment reports as stipulated in the Contractual Agreement.

4. The contractor shall prepare all deliverables in accordance with the Quality Management Plan for the contract.

V. NOTICE REGARDING GUIDANCE PROVIDED UNDER THIS TASK ORDER.

Guidance is strictly limited to technical and analytical support. The contractor shall not engage in activities of an inherent governmental nature such as the following:

(1) Formulation of Agency policy
(2) Selection of Agency priorities
(3) Development of Agency regulations

If the contractor receives any instructions from an EPA staff person that the contractor ascertains to fall into any of these categories or goes beyond the scope of the contract or work assignment, the contractor shall immediately notify the COR. The contractor shall also ensure that work under this Work Assignment does not contain any apparent or real personal or organizational conflict of interest. The contractor shall certify that no conflicts exist at the time the proposal is submitted to the EPA.

VII. EPA CONTACT INFORMATION.

Copies of all correspondence pertaining to the performance of this work assignment shall be sent electronically to the COR.

Work Assignment Manager	**Alternate WAM**
Linda Phillips US EPA (8623P) National Center for Environmental Assessment Office of Research and Development U.S. Environmental Protection Agency 1200 Pennsylvania Ave. NW Washington, DC 20460 Telephone #: (703) 347-0366 FAX #: (703) 347-8690 Email: phillips.linda@epa.gov	Jacqueline Moya US EPA (8623P) National Center for Environmental Assessment Office of Research and Development U.S. Environmental Protection Agency 1200 Pennsylvania Ave. NW Washington, DC 20460 Telephone #: (703) 347-8539 FAX #: (703) 347-8694 Email: moya.jacqueline@epa.gov

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 3-51

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-14-001	11/01/2013 To 10/31/2017	Support for STPC
	Base Option Period Number 3	

Contractor	Specify Section and paragraph of Contract SOW
ICF INCORPORATED, L.L.C.	E. Risk Assessment Support Meetings

Purpose:
- [X] Work Assignment
- [ ] Work Assignment Amendment
- [ ] Work Plan Approval
- [ ] Work Assignment Close-Out
- [ ] Incremental Funding

Period of Performance: From 11/01/2016 To 10/31/2017

Comments:

☐ Superfund — Accounting and Appropriations Data — [X] Non-Superfund

SFO (*Max 2*): ☐

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

Contract Period: 11/01/2013 To 10/31/2017 — Cost/Fee: — LOE:

This Action:

Total:

Work Plan / Cost Estimate Approvals

Contractor WP Dated: — Cost/Fee — LOE:

Cumulative Approved: — Cost/Fee — LOE:

Work Assignment Manager Name: Thomas O'Farrell (Signature) (Date)	Branch/Mail Code: Phone Number: 703-347-8085 FAX Number:
Project Officer Name: Melissa Revely-Wilson (Signature) (Date)	Branch/Mail Code: Phone Number: 919-541-0207 FAX Number:
Other Agency Official Name: (Signature) (Date)	Branch/Mail Code: Phone Number: FAX Number:
Contracting Official Name: William Yates (Signature) (Date)	Branch/Mail Code: Phone Number: 513-487-2055 FAX Number:

PERFORMANCE WORK STATEMENT
Contract # EP-C-14-001
WA 3-51

TITLE: Meeting Support for Science and Technology Policy Council and Scientific Support Panel Staff and Related Interagency Activities in Support of the EPA Science Advisor

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NOTE: This work assignment is a follow-on to work performed in the Year 2 Option Period under Work Assignment # 2-51. The work continues from Task 1 through Task 5 during this Year 3 Option Period under Work Assignment 3-51. This PWS describes only Tasks 1-5. Tasks 1-5 from Option Year 2 have been completed.

Specify Section & Paragraph SOW: E. Risk Assessment Support - Meetings

PERIOD OF PERFORMANCE: CO Approval – October 31, 2017

BACKGROUND

The EPA Science Advisor convenes and chairs the EPA Science and Technology Policy Council (STPC) and Community of Science Staff, which is comprised of senior managers from EPA Offices and Regions. The official STPC representatives are at the Deputy Assistant Administrator and Deputy Regional Administrator level and appropriate level for Offices within the Office of the Administrator. The Science Advisor's priorities for the STPC dovetail with interagency activities, including, but not limited to, the White House Office of Science and Technology Policy (OSTP), National Academies, Government Accountability Office and the Office of Management and Budget. The STPC is supported by a Scientific Support Panel (consisting of Agency Senior Science Advisors) and a small staff within the Office of the Science Advisor (OSA).

TASKS

Establish Communication Within 3 days after award of this WA, the Contractor shall schedule a conference call (not to exceed 1 hour) with the WAM and appropriate contractor staff to clarify outstanding questions and confirm the schedule and specific tasks. The Contractor shall prepare a written work plan describing how the tasks in this PWS will be performed, including a schedule, budget, level of effort, and qualifications of personnel. To facilitate timely preparation of the work plan, a kick-off meeting shall be held (in person and/or by phone) between the Contractor and the EPA WA Manager (WAM) to clarify or address questions. The Contractor shall maintain communication with the WAM through weekly phone calls or email updates.

The Contractor shall also prepare a schedule for deliverables to ensure all materials are properly reviewed, approved, and disseminated.

1) The Science Advisor convenes quarterly meetings of the STPC. The Science Advisor may convene additional meetings of the STPC to address specific topics (estimate two special STPC meetings). The EPA Work Assignment (TO) COR will provide meeting logistical information to the contractor in advance. The contractor shall attend the meetings in person, record the meeting and prepare a concise meeting summary report consisting of action items, decisions, and brief summary of discussions. The contractor shall prepare draft and final meeting summary reports based on comments received from EPA WAM, Technical Representative and STPC staff.

2) The Scientific Support Panel staff convenes up to eight meetings of the Scientific Support Panel each

year. The EPA WAM will provide meeting logistical information to the contractor in advance. The contractor shall attend the meetings by phone, record the meeting and prepare a concise meeting summary report consisting of action items, decisions, and brief summary of discussions. The contractor shall prepare draft and final meeting summary reports based on comments received from EPA WAM, Technical Representative and Community of Science staff.

3) The STPC staff convenes up to 4 meetings of the Peer Review Advisory Group, which reports to the STPC. The EPA WAM will provide meeting logistical information to the contractor in advance. The contractor shall attend the meetings by phone, record the meeting and prepare a concise meeting summary report consisting of action items, decisions, and brief summary of discussions. The contractor shall prepare draft and final meeting summary reports based on comments received from EPA WAM, Technical Representative and STPC staff.

4) The STPC and Scientific Support Panel staff assist ad hoc committees that may be formed at the discretion of the Science Advisor. The contractor shall provide assistance as needed for tasks assigned via Technical Direction from the EPA WAM. Contractor assistance may include: occasional note taking for technical discussions, technical editing of reports, and development of documents, including text, tables, and figures. (Estimate support for 4 ad hoc meetings, technical editing of 3 documents, less than 150 pages each).

5) STPC activities may require support to develop communication and outreach materials for internal and external stakeholders.

DELIVERABLES

1) Draft meeting summary reports within two (2) days.

2) Provide EPA WAM with electronic link to the audio recording for STPC meetings within 5 days.

3) Provide final documents and reports within five (5) days after receipt of EPA comments on draft reports, meeting summary reports, or other task outputs.

CONFLICT OF INTEREST

The contractor shall disclose any conflict of interest regarding this work.

ACCEPTANCE CRITERIA

Deliverables shall be provided to the EPA WAM in accepted Agency format and be of high quality. Deliverables shall be prepared using software compatible with current ORD computer systems. In some cases, the draft document will be sufficient for the purposes of the STPC staff. Deliverables shall be submitted electronically to the EPA WAM via e-mail as well as hard copy (when requested).

MANAGEMENT CONTROLS

Periodic meetings between the EPA and contractor staff are encouraged to discuss any questions that may arise during performance or completion of this TO. At the EPA WAM's discretion, these meetings may occur via teleconference or video conferences. The contractor shall document these meetings and submit copies of this correspondence to the EPA TO.

The EPA WAM may identify one or more EPA technical representatives for this TO. Interaction between the contractor and any EPA technical representative(s) designated by the EPA WAM is solely for the purpose of

presenting and discussing the information, analyses, results, or presentations related to this TO. The interaction will be technical communication vice technical direction. Per the technical direction clause EPAAR 1552.237-71 of the contract, the EPA PO and the EPAWAM or alternate EPA WAM are the sole representatives of the Contracting Officer authorized to provide technical direction.

WORK ASSIGNMENT COR (WAM):

Thomas O'Farrell
Office of Science Advisor
U.S. EPA (8105R)
Office of Research and Development
1200 Pennsylvania Avenue, NW
Washington, D.C. 20460
Telephone: (202) 564-8451
Fax: (202) 564-2070

ALTERNATE WAM:

Greg Susanke
Office of Science Advisor
U.S. EPA (8105R)
Office of Research and Development
1200 Pennsylvania Avenue, NW
Washington, DC 20460
Telephone: (202) 564-9945
Fax: (202) 564-2070

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 3-53

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-14-001	11/01/2013 To 10/31/2017	Development of Economic Scenar
	Base Option Period Number 3	

Contractor: ICF INCORPORATED, L.L.C.

Specify Section and paragraph of Contract SOW: D. Analysis, Document and Issue Paper Preparation

Purpose:
- ☒ Work Assignment
- ☐ Work Assignment Amendment
- ☐ Work Plan Approval
- ☐ Work Assignment Close-Out
- ☐ Incremental Funding

Period of Performance: From 01/11/2016 To 10/31/2017

Comments:

☐ Superfund — Accounting and Appropriations Data — ☒ Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (*Max 2*) ☐

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

	Cost/Fee:	LOE:
Contract Period: 11/01/2013 To 10/31/2017		
This Action:		
Total:		

Work Plan / Cost Estimate Approvals

	Cost/Fee	LOE:
Contractor WP Dated:		
Cumulative Approved:		

Work Assignment Manager Name: Anne Grambsch (Signature) (Date)	Branch/Mail Code: Phone Number: 703-347-8521 FAX Number:
Project Officer Name: Melissa Revely-Wilson (Signature) (Date)	Branch/Mail Code: Phone Number: 919-541-0207 FAX Number:
Other Agency Official Name: (Signature) (Date)	Branch/Mail Code: Phone Number: FAX Number:
Contracting Official Name: William Yates (Signature) (Date)	Branch/Mail Code: Phone Number: 513-487-2055 FAX Number:

PERFORMANCE WORK STATEMENT
CONTRACT NO. EP-C-14-001
WA 3- 53

TITLE: Development of Economic Scenarios

Specify Section & Paragraph SOW:
B. Risk Assessment Methods Research and Development
D. Analysis, Document and Issue Paper Preparation
E. Risk Assessment Support: 1. Science Writing, Risk Communication and Training
G. Literature Search

PERIOD of PERFORMANCE: CO approval through 10/31/2017

I. PURPOSE

The purpose of this work assignment is to provide scientific and technical support for the development of economic development scenarios to the U.S. Environmental Protection Agency's (hereinafter EPA or Agency) National Center for Environmental Assessment (NCEA). This work assignment is consistent with the purpose and scope of Contract EP-C-14-001 and includes summarizing the relevant literature and preparing background material on the current state of knowledge with respect to economic development projections, updating information on valuation of climate change impacts, updating background white papers on methods and models, and compiling information on existing federal government resources. This effort is intended to provide technical information for use in future assessments of impacts, including National Climate Assessments, and support Agency efforts to adapt to climate change risks.

II. BACKGROUND

Future economic development plays a critical role as both a driver of global and environmental change and as a determinant of vulnerability to that change. More specifically, scenarios of future economic development are needed for climate change assessments in general, and health assessments in particular. The US Global Change Research Program (USGCRP) National Assessments led to concerted efforts to develop a range of scenarios and projections in order to better understand the impact of climate change on the US and the national's capability to adapt. While there are well-established methods for developing projections, the USGCRP has not engaged in a sustained effort to develop economic development scenarios that are regional in focus but consistent with global-scale climate scenarios (e.g., SRES Scenarios, RCP scenarios, SSP scenarios). Developing scenarios of changes at fine spatial scales, including economic development, would support multiple agency needs including:

- Assessments of climate change impacts on human health, on water resources, on agriculture and forestry, coastal areas, natural resources, etc. and
- Determining vulnerability of people and infrastructure to climate and weather extremes.

The lack of information about the costs, benefits, and efficiency of actions to respond to climate change risks has been identified as a critical unknown. A key element of support for decision-making is an understanding of the magnitude and distribution across the population of these risks and impacts so that the feasibility, tradeoffs, and equity implications implicit in any decision can be balanced and compared. Several federal agencies have developed models and prepared guidelines for conducting such analyses (e.g., EPA's Guidelines for Preparing Economic Analysis (U.S. EPA, 2000), NOAA's Report of the NOAA Panel on Contingent Valuation (Arrow et

al., 1993); USACE's Review of Monetary and Non-Monetary Valuation of Environmental Investments (Feather et al., 1995)).

NOTE: This work assignment is a follow-on to work performed in the Year 2 Option Period under Work Assignment # 2-53. Previous work under this Contract (WA 2-53) resulted in:

- Content for a website to be hosted by the USGCRP, including 1) Background text on economic impacts (general framework), economic effect pathways, and measurement techniques for each sector of the National Climate Assessment and 2) Agency economic resource pages;
- Concept and design for a web-based portal,
- Support and background materials for an interagency workshop held in April 2016
- A final report entitled Multi-Scale Economic Methodologies and Scenarios Workshop
- A draft section of a journal article

This Work Assignment is for continuing support during Option Year 3 to:

- Complete article for submission to a journal

III. STATEMENT OF WORK

Task 1: Establish Communication

Within 3 days of start date of this WA, the Contractor shall schedule a conference call (not to exceed 1 hour) with the WAM and appropriate contractor staff to clarify outstanding questions and confirm the schedule and specific tasks.

Task 2: Work Plan and Staffing Plan,

The Contractor shall prepare a Technical Work Plan describing how the work outlined in this Performance Work Statement will be performed, including deliverables, a schedule, budget, and level of effort. The Contractor shall also prepare a Staffing Plan, which shall be submitted as part of the Work Plan that shows assigned personnel by task and the qualifications of the proposed personnel. The Contractor shall provide expertise in the areas of non-market valuation techniques, integrated assessment modeling, economic models, and models for projecting and estimating climate change impacts. The QAPP was prepared under the previous Work Assignment.

Task 3: Finalize article

Under the previous work assignment, the Contractor, working with DOE and EPA staff and the science lead, participated in discussions regarding a journal publication and prepared a draft of a section of the article. The Contractor shall participate in additional teleconferences, and based upon feedback from DOE, EPA and the science lead shall revise and prepare a final version of the section. The Contractor shall also participate in discussions regarding the publication and provide technical editing support for other sections of the publication. The Contractor shall submit the final article to an appropriation journal for publication.

Deliverable 1: Submission of final article

IV. ANTICIPATED DELIVERABLES

All products by the Contractor must be of high quality, written in a clear concise style, with a logical organization and presentation. Deliverables shall be provided to EPA in electronic formats compatible with EPA-supported software (e.g., Excel spreadsheets, Word documents, BMDS accessory files [*.(d), *.out, *opt, *.ssn]).

V. DELIVERABLES AND SCHEDULE

Task 1. Initial Conference Call	3 days after award of Work Assignment
Task 2. Staffing Plan, and QAPP	20 days after award of Work Assignment
Task 3. Finalize article	2 weeks are receipt of WAM comments

Note: All days are calendar days.

VI. MANAGEMENT CONTROLS

1. All deliverables shall be reviewed for conformance to the requirements of this work assignment before being approved as final.

2. The contractor shall comply with other applicable requirements for final work assignment reports stipulated in contract.

VII. NOTICE REGARDING GUIDANCE PROVIDED UNDER THIS PROJECT

Guidance is strictly limited to technical and analytical support. The contractor shall not engage in activities of an inherent governmental nature such as the following:

(1) Formulation of Agency policy
(2) Selection of Agency priorities
(3) Development of Agency regulations

Should the contractor receive any instruction from an EPA staff person that the contractor ascertains to fall into any of these categories or goes beyond the scope of the contract or work assignment, the contractor shall immediately contact the PO, WAM or CO

VIII. SPECIAL CONDITIONS AND ASSUMPTIONS

The contractor shall hold a conference call with the EPA WAM at the initiation of the work assignment, and shall provide a bi-weekly update to the WAM by telephone for the duration of the work assignment, in addition to the standard reporting requirements of the contract.

IX. EPA CONTACT INFORMATION

Copies of all correspondence pertaining to the performance of this work assignment shall be sent to the PO.

Work Assignment Manager (WAM)
Anne Grambsch
U.S. EPA
Mail Code 8601 P
Washington, DC 20460
(703) 347-8521; FAX (703) 347- 8694
grambsch.anne@epa.gov

Alternate Work Assignment Manager (WAM)
Britta Bierwagen
U.S. EPA

Mail Code 8601 P
Washington, DC 20460
(703) 347-8613; FAX (703) 347- 8694
Bierwagen.Britta@epa.gov

Appendix A

Quality Assurance Instructions for Contractors Citing Secondary Data

Section 515 of the Treasury and General Government Appropriations Act for fiscal year 2001 directed the Office of Management and Budget (OMB) to issue guidelines to all Federal agencies to ensure and maximize the quality, objectivity, utility, and integrity of the information they disseminate. This law and the OMB guidance subsequently issued in 67 FR 8452 (02/22/02) underscore the need for EPA/NCEA to assess the quality and credibility of the secondary research information cited in its assessment documents.

Secondary research information is defined as information that was originally produced for one purpose but is now being recompiled or reassessed for a different purpose. Secondary research information usually originates from such primary sources as journal articles, books, government and industry reports, databases, and models. The set of processes that follows serves as a guide to evaluate the strength of secondary data gathered from these primary sources.

The Contractors must list the sources for the references cited in his/her document chapters or sections. The source list will include but not be limited to the names of any commercially available or local databases searched by computer or by hand, the search terms and search strategy used, and the time period of the search. List any print sources like books or journal articles which provided references. List any sources of raw data.

After fully reporting all of the reference sources, identify the most relevant information or key studies among the references you cite and critically evaluate them. Key studies are those most crucial or pivotal to answer the research questions for the project. The key study may have positive or negative results and may even be all that is currently available on the research topic, but the key study is integral to any discussion of the topic. Sometimes, the key study is not recognizable until all of the literature is gathered and evaluated. Key studies should exhibit at least most of the general attributes defined below:

FOCUS: the work not only addresses the area of inquiry under consideration but also contributes to its understanding;
VERIFY: the work is consistent with accepted knowledge in the field or, if not, the new or varying information is documented within the work; the work fits within the context of the literature and is intellectually honest and authentic;
INTEGRITY: Is the work structurally sound? In a piece of research, is the design or research rationale logical and appropriate?
RIGOR: the work is important, meaningful, and non-trivial relative to the field and exhibits sufficient depth of intellect rather than superficial or simplistic reasoning;
UTILITY: the work is useful and professionally relevant; it makes a contribution to the field in terms of the practitioners' understanding or decision-making on the topic.
CLARITY: Is it written clearly and appropriately for the nature of the study?

Use the check list on the following page to evaluate the key studies.

DATA CHECKLIST FOR EVALUATING A STUDY

1.) Bibliographic identification of the study.

Study Identifiers:
Author(s):
Title:
Study Citation:
Storage location (e.g., library, facility archive, personal archive):

2.) Why is the study key to the particular project? (For example, is the study an example of new research or confirmation of previous work? Is the study's population larger or followed for a longer period of time than before, is the methodology better than other studies or corrective of problems in previous studies, or do the results provide new insight into the problem?)

3.) Summarize the study structure and methodology. What sampling techniques and statistical tests are used?

4.) Potential problem areas in the study; consider: study design, factors occurring within and outside of the study which may affect its validity, sampling errors, and any other perceived weaknesses.

5.) Do any data used from sources outside of the study seem reliable and generally free of measurement error? Discuss and give examples.

6.) Evaluate the study in terms of the appropriateness of the analytical methodology. In responding, consider the following questions:

Are research questions clearly stated; dependent and independent variables clearly defined?

Do the authors explain the type of data obtained from measures of the variables?

Are statistical methods adequately described; are they justified?

Is a source provided for the any statistical software used to analyze the data?

Is the purpose of the analysis clear?

Are any scoring systems described?

Are potential confounders adequately controlled for in the analysis?

Are analytic specifications of the variables consistent with the evaluation questions or hypotheses under study?

Is the unit of analysis specified clearly?

If statistical tests are used to determine comparability or difference, are p values provided; is the practical significance of these findings, as contrasted with the statistical significance, discussed?

7.) Evaluate the study's results. Consider the following questions:

Are study questions (objectives, hypotheses) clear?

Are all study questions answered?

Are negative findings presented?

Are missing data explained?

Are text and tables, figures, and graphs consistent?

8.) Evaluate the study's conclusions. Consider the following questions:

Are the conclusions based on the study's data in that findings are applied only to the sample that was included in the research?

When the authors compare their findings with those from another study, do the authors demonstrate the similarity of the two studies?

Does the author discuss limitations of design, sampling, data collection, etc.?

To what extent do the limitations affect one's confidence in the conclusions?

9.) How strong is the study, overall; relative to other similar studies? Do its weaknesses jeopardize its being a key study, or is it usable despite the reservations?

PERFORMANCE WORK STATEMENT
CONTRACT NO. EP-C-14-001
WA 3-56

TITLE: Technical Support for Curation of Toxicity Reference Database (ToxRefDB)

Specify Section & Paragraph SOW: C. Risk Assessment Data Bases and Computer Tools

PERIOD of PERFORMANCE: CO approval through 10/31/2017.

I. PURPOSE.

The purpose of this work assignment is to obtain technical support services to the US Environmental Protection Agency's (EPA), Office of Research and Development (ORD), National Center for Computational Toxicology (NCCT) to curate available legacy toxicity information on repeat-dose short-term and long-term toxicity studies into the Toxicity Reference Database (ToxRefDB).

II. BACKGROUND AND OBJECTIVES.

The National Center for Computational Toxicology (NCCT) is responsible for developing computational tools and solutions for improving environmental risk assessments and regulatory decisions. NCCT is developing methodologies to characterize chemicals based on known and predicted toxic effects. As a part of this effort, the NCCT's ToxRefDB project (http://epa.gov/ncct/toxrefdb/) has compiled thousands of in vivo animal toxicity studies on hundreds of chemicals. ToxRefDB supports NCCT's ToxCast project by providing in vivo data to anchor in vitro and in silico models while also serving as a public reference tool.

III. STATEMENT OF WORK.

The contractor shall be responsible for completion of three tasks. A summary of each task is provided below, including the time frame during which the task shall be completed. This is a roll-over from WA 2-56.

Task 1. The contractor shall establish communication, submit a work plan, and arrange for routine updates for the EPA Work Assignment Contracting Officer's Representative (WA COR).

The contractor shall schedule an initial conference call **within 1 week** after the receipt of the work assignment. The call shall include the COR and relevant members of the ICF team.

Deliverable 1: The contractor shall arrange a conference call with the COR, **within 1 week after the receipt of the work assignment.**

Task 2. The contractor shall review the accuracy of the ToxRefDB study file with the associated study report(s) including capturing the testing status for all observations

The ToxRefDB stores roughly 6000 animal toxicology studies in a relational database with controlled vocabularies. Over 1000 chemicals have at least one study in the database. A subset of these studies, roughly 3000, have NOAEL/LOAEL determinations. For each LOAEL, a set of effects were assigned to the LOAEL as being critical. The LOAELs and associated effects have all been entered and tagged in the database previously.

The contractor shall assist EPA in reviewing the LOAELs and associated effects for accuracy in the database to ensure the quality of the following tasks as well as catalog the testing status of all observations (e.g., tested, not tested, not reported). The contractor shall provide a monthly summary of the studies reviewed and any edits performed.

1. Specifically, the contractor will open the source study documents, housed at the EPA, and compare stated NOAEL/LOAEL levels in the documents with levels listed in the **ToxRefDB outputted file(s).** The critical effects **and all other treatment-related effec**ts listed can be compared and reviewed in a similar manner. The EPA estimates the review process to take roughly 30 minutes per study, on average.
2. Additionally, the contractor shall capture the testing status of all study observations provided for in the **ToxRefDB outputted file(s)**. The EPA estimates the review process to take roughly 30 minutes per study, on average.

Deliverable 2: The contractor shall provide a **monthly** summary of the studies reviewed and any edits performed.

Task 3. The contractor shall enter quantitative data for all effects.

The NOAEL/LOAEL determinations and the associated critical effects have been entered and quality controlled (task 2) **as well as all other treatment-related effects** in ToxRefDB. With the goal of performing dose-response modeling (benchmark dose modeling) to determine more quantitative points of departure, the contractor shall enter the dose-response data (incidence and/or mean +/- standard deviation, and sample size**, as well as any other necessary fields mutually decided)** for each treatment group, including the control group, for all effects tagged **treatment-related and/or critical** in the study.

For example, a study was run at 3 doses plus controls with male and female groups. The NOAEL was established at 10 mg/kg/day and the LOAEL at 100 mg/kg/day based on liver weight gain in males and females, liver hypertrophy in males and females, and thyroid hyperplasia in the males. Additionally, spleen weight increase was observed and deemed treatment-related in the high dose group at 1000 mg/kg/day. With this example, the contractor shall enter the group mean and standard deviation for liver and spleen weights and incidence information for liver hypertrophy and thyroid hyperplasia at each dose level and for the control group**(s)**.

The EPA estimates the primary data extraction to take roughly 2 hours per study, on average, with a secondary review taking 1 hour per study on average.

Deliverable 3: The contractor shall provide the COR with a monthly summary of the number of studies with completed quantitative data entry as well as any specific comments regarding special cases or anomalies with data entry.

IV. SUMMARY TIME TABLE.

Task	Deliverable	Time frame
1	Establish communication via conference call	Within 1 week after receipt of work assignment
2	Monthly summary of studies reviewed	Monthly
3	Monthly summary of studies with quantitative data entered	Monthly

1. The contractor shall be responsible for obtaining a conflict of interest certification for any subcontractor services.
2. All deliverables shall be in conformance with the requirements of the work assignment before such deliverables are approved as final. Electronic copy of all deliverable shall be sent to the EPA WA COR.
3. The contractor shall comply with other applicable requirements for final work assignment reports as stipulated in the Contractual Agreement.
4. The contractor shall prepare all deliverables in accordance with the Quality Management Plan for the contract.

V. MANAGEMENT CONTROLS

1. All deliverables shall be reviewed for conformance to the requirements of this work assignment before being approved as final.
2. The contractor shall comply with other applicable requirements for final work assignments reports stipulated in contract.

VI. NOTICE REGARDING GUIDANCE PROVIDED UNDER THIS TASK ORDER.

Guidance is strictly limited to technical and analytical support. The contractor shall not engage in activities of an inherent governmental nature such as the following:

1. Formulation of Agency policy
2. Selection of Agency priorities
3. Development of Agency regulations

If the contractor receives any instructions from an EPA staff person that the contractor ascertains to fall into any of these categories or goes beyond the scope of the contract or work assignment, the contractor shall immediately notify the WA COR. The contractor shall also ensure that work under this Work Assignment does not contain any apparent or real personal or organizational conflict of interest. The contractor shall certify that no conflicts exist at the time the proposal is submitted to the EPA.

VII. EPA CONTACT INFORMATION.

Copies of all correspondence pertaining to the performance of this work assignment shall be sent electronically to the Work Assignment Contracting Officer's Representative (WA COR).

WA COR	**Alternate WA COR**
Matthew Martin National Center for Computational Toxicology Office of Research and Development U.S. Environmental Protection Agency 109 T.W. Alexander Dr. (B205-01) RTP, NC 27711 Telephone #: (919) 541-4101 FAX #: (919) 541-1194 Email: martin.matt@epa.gov	Sandra Roberts National Center for Environmental Assessment Office of Research and Development U.S. Environmental Protection Agency 109 T.W. Alexander Dr. (B205-01) RTP, NC 27711 Telephone #: (919) 541-3850 FAX #: (919) 541-1194 Email: roberts.sandra@epa.gov

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 3-56

☐ Other ☒ Amendment Number: 000001

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-14-001	11/01/2013 To 10/31/2017 Base Option Period Number 3	Curation of Toxicity Reference

Contractor: ICF INCORPORATED, L.L.C.

Specify Section and paragraph of Contract SOW:

Purpose:
- ☐ Work Assignment
- ☒ Work Assignment Amendment
- ☐ Work Plan Approval
- ☐ Work Assignment Close-Out
- ☐ Incremental Funding

Period of Performance: From 11/01/2016 To 10/31/2017

Comments:
Remove Matthew Martin as Alt. COR - left agency. All other terms and conditions remain unchanged.

☐ Superfund — Accounting and Appropriations Data — ☒ Non-Superfund

SFO (*Max 2*) ☐

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

	Cost/Fee:	LOE:
Contract Period: 11/01/2013 To 10/31/2017		
This Action:		
Total:		

Work Plan / Cost Estimate Approvals

	Cost/Fee	LOE:
Contractor WP Dated:		
Cumulative Approved:		

Work Assignment Manager Name: Sandra Roberts (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	919-541-3850
	FAX Number:	
Project Officer Name: Melissa Revely-Wilson (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	919-541-0207
	FAX Number:	
Other Agency Official Name (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	
	FAX Number:	
Contracting Official Name: William Yates (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	513-487-2055
	FAX Number:	

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 3-61

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-14-001	11/01/2013 To 10/31/2017	Technical Support
	Base Option Period Number 3	

Contractor: ICF INCORPORATED, L.L.C.

Specify Section and paragraph of Contract SOW: E1 and E2

Purpose:
- [X] Work Assignment
- [ ] Work Assignment Amendment
- [ ] Work Plan Approval
- [ ] Work Assignment Close-Out
- [ ] Incremental Funding

Period of Performance: From 11/01/2016 To 10/31/2017

Comments:

☐ Superfund — Accounting and Appropriations Data — [X] Non-Superfund

SFO (*Max 2*): ☐

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

	Cost/Fee	LOE
Contract Period: 11/01/2013 To 10/31/2017		
This Action:		
Total:		

Work Plan / Cost Estimate Approvals

	Cost/Fee	LOE
Contractor WP Dated:		
Cumulative Approved:		

Work Assignment Manager Name: Nica Louie	(Signature)	(Date)	Branch/Mail Code: / Phone Number: 703-347-8125 / FAX Number:
Project Officer Name: Melissa Revely-Wilson	(Signature)	(Date)	Branch/Mail Code: / Phone Number: 919-541-0207 / FAX Number:
Other Agency Official Name	(Signature)	(Date)	Branch/Mail Code: / Phone Number: / FAX Number:
Contracting Official Name: William Yates	(Signature)	(Date)	Branch/Mail Code: / Phone Number: 513-487-2055 / FAX Number:

PERFORMANCE WORK STATEMENT
CONTRACT NO. EP-C-14-001
WA 3-61

TITLE: Technical Support for the National Center for Environmental Research's (NCER) Water, Health, and Innovation Division (WHID)

Specify Section & Paragraph SOW:
E1, Risk Assessment Support; Science Writing, Risk Communication and Training
E2, Risk Assessment Support; Administration and Technical Support for Meetings

PERIOD OF PERFORMANCE: CO award to 10/31/17

I. PURPOSE

The purpose of this Work Assignment is to provide services to the U.S. Environmental Protection Agency's (hereinafter EPA or Agency) Water, Health, and Innovation Division (WHID) of the National Center for Environmental Research (NCER) for administrative and technical support to maximize the utility of the extramural research that it funds. The contractor shall only perform those activities assigned by the EPA WA COR through Technical Directives. At times the contractor shall need to directly contact the Principal Investigators (i.e., the extramural researchers) or members of the WHID to either collect additional information or to clarify information.

Under this work assignment, the contractor shall:

(1) Provide technical, information transfer, communications and logistical support for program, and progress review workshops, EPA and ORD science meetings involving its investigator initiated research grants, as well as other meetings and workshops supported by NCER management.
(2) Assist the WHID in developing synthesis reports to summarize research across all projects within a single RFA; across multiple RFAs within a single research area; or across all research areas. For the purposes of this work assignment, deliverables are called Human Health Synthesis Reports.
(3) Support the EPA People, Prosperity and the Planet (P3) program which is a college competition that engages students to define challenges for designing and developing sustainability solutions for human health, risk and environmental challenges. In its 12th year, the program has engaged thousands of students and faculty through grant awards and a national competition for additional funds to support further development, testing and enterprise foundation.

II. BACKGROUND

NCER's Water, Health, and Innovation Division seeks to promote extramural research as part of the Science to Achieve Results (STAR) program that will enhance scientific knowledge about the various ways that environmental pollutants adversely affect public health and the environment. Given EPA's critical mission of protecting human health – as well as the rapid emergence of research using new scientific understanding and technologies – the Human Health Team is well positioned to play a pivotal role in aggregating, synthesizing and publicizing the findings of funded research. The research generates findings related to environmental health risks and issues and multiple sources of environmental stressors. Such findings contribute to a better characterize complex exposures and/or risk from multiple stressors (e.g., environmental, socio-economic), sources and routes that influence human health outcomes, highlighting health concerns pertaining to children's environmental health, cumulative risk and environmental justice, among other Agency priorities.

Under this work assignment, the contractor shall:

a) Continue with efforts to prepare a synthesis report summarizing key successes and findings from the EPA/NIEHS Children's Centers Program that has been jointly funded for more than 16 years. The research conducted under this program covers the entire environmental health paradigm from exposure to health effects, risk assessment, and to managing those risks, including community outreach, engagement and translation. The report will be approximately 30-40 pages, and build on the report: A Decade of Children's Environmental Health Research (http://www.epa.gov/ncer/publications/research_results_synthesis/ceh_report_508.pdf). The contractor should use creative methods for conveying research findings and progress such as in the summary "Celebrating 25 Years of the Superfund Program" (http://www.niehs.nih.gov/research/supported/assets/docs/r_s/srp_25th_anniversary_commemorative_booklet_508.pdf).

b) Prepare a synthesis report (approximately 30-40 pages in length) summarizing key successes and findings from the Environmental Public Health Indicators research portfolio, which currently includes 3 RFAs (a total of 20 grants) issued in 2006, 2007, and 2009. The research conducted under this program has sought to develop new or improved EPHIs to build linkages between environmental hazards, human exposures, and public health disease outcomes. EPHIs can be used for long-term tracking and surveillance of environmental public health, making better informed decisions, and assessing the actual impacts of environmental risk management decisions. General information about this portfolio can be found at www.epa.gov/ncer/ephi.

c) Prepare a synthesis report (approximately 10-20 pages in length) summarizing key successes and findings from the joint EPA-NIMHD Centers of Excellence on Environment Health Disparities, which includes a total of 10 supplemental grants (for a total of $7.5 million) provided to existing NIMHD Centers to add environmental health components to their current projects. The Centers support a transdisciplinary network of excellence in health disparities research that engages in the complex interaction of biological, social and environmental determinants of population health. A poster link for the Centers can be found here or at https://www.epa.gov/sites/production/files/2015-09/documents/epa-nimhd_ehd_centers_poster-2015_bosc_082415.pdf

d) Plan and implement the annual meeting for the P3 Phase I grantees to present their projects at the USA Science and Engineering festival being held April 16th and 17th, 2016 (http://www.usasciencefestival.org/)

III. STATEMENT OF WORK

Task 1: Establish Communication

Within 3 days of start date of this WA, the Contractor shall schedule a conference call (not to exceed 1 hour) with the WAM and appropriate contractor staff to clarify outstanding questions and confirm the schedule and specific tasks.

Task 2: Work Plan, Staffing Plan, and Quality Assurance Project Plan (QAPP)

The Contractor shall prepare a Technical Work Plan describing how the work outlined in this Performance Work Statement will be performed, including deliverables, a schedule, budget, and level of effort. The Contractor shall also prepare a Staffing Plan, which shall be submitted as part of the Work Plan, which shows assigned personnel by task and the qualifications of the proposed personnel. The Contractor shall provide expertise in administrative and technical support to a conference. The contractor shall review and submit the QAPP prepared under Work Assignment 1-61 with any necessary revisions (only minor revisions are expected. The QAPP should describe the necessary QA procedures, quality control activities and other technical activities that will be implemented to ensure that the synthesis report is factually correct, that any interpretation of results or findings are accurate and that the report is prepared to the highest quality.

TASK 3: HUMAN HEALTH SYNTHESIS REPORTS:
Human Health Synthesis Reports Contractor will assist the Water, Health, and Innovation Division in developing and drafting reports and short research summaries with graphics (e.g. one page flyers, fact sheets pamphlets and brochures) to synthesize the extramural research funded by the Team. Contractors may be asked to assist in developing a synthesis report and short summaries to summarize research across all Projects within a single RFA; across multiple RFAs within a single Research Area; or across all Research Areas.

Task 3.1. Synthesis report - EPA/NIEHS Children's Centers Program – 15 years of success

The contractor shall continue to prepare the 15 year synthesis report summarizing key successes and findings from the EPA/NIEHS Children's Centers Program that has been jointly funded for more than 16 years. EPA has provided to the contractor results from research on successes from the Centers conducted by NIEHS that may guide how this document is formulated. The work group established under Work Assignment 1-61 includes Children's Centers Directors and staff, EPA and NIEHS program and other staff such as the Communications Department will continue to identify the key areas of focus and to assist in collection of materials needed.

To write a report at the high level of quality needed, the effort will require staff with education backgrounds at both PhD and Master's degree levels with expertise in public and/or environmental health.

Staff at the PhD level will need to evaluate the important research results and their potential significance for achieving outcomes in the years to come. It may be necessary to utilize outside resources to evaluate the impact of the Children's Centers program. Staff at the Master's degree level will review grants reports, and other materials supplied by EPA, draft the summary, review comments and finalize the report.

The contractor shall:

a) Review materials provided by EPA and prepare a proposed draft outline
b) Arrange/participate in the synthesis report workgroup call and prepare action items from the calls
c) Assist the workgroup define the parameters for the report and help identify creative methods for sharing data, findings and other information.
d) Prepare revised outline and review with EPA and workgroup members
e) Where necessary, contact current and previously funded Children's Centers to collect information identified by the workgroup.
f) Prepare synthesis report based on revised outline.

Task 3.2. Synthesis report – STAR Environmental Public Health Indicators: A Decade of Research
The contractor shall continue to prepare the synthesis report summarizing key successes and findings from the EPHI research portfolio that has been funded for the past 10 years. EPA will provide to the contractor results from research conducted by the EPHI grantees and other information that may guide how this document is formulated.

In order to write a report at the high level of quality needed, the effort will require staff with education backgrounds at both PhD and Master's degree levels with expertise in public and/or environmental health.

Staff at the PhD level will need to evaluate the important research results and their potential significance for achieving outcomes in the years to come. It may be necessary to utilize outside resources to evaluate the impact of the pilot EHD Centers. Staff at the Master's degree level will review grants reports, and other materials supplied by EPA, draft the summary, review comments and finalize the report.

The contractor shall:

a) Review materials provided by EPA and prepare a proposed draft outline for review by the EPA Project Officer.
b) Define the parameters for the report and help identify creative methods for reporting research findings and other information.
c) Where necessary, contact current and previously funded grantees to collect required data and information.
d) Prepare a draft of the synthesis report for review by the EPA Project Officer based on the report outline.
e) Revise the draft report based on comments from the EPA Project Officer and develop the final report.

Task 3.3. Synthesis report – EPA-NIMHD Centers of Excellence on Environment and Health Disparities

The contractor shall continue to prepare the synthesis report summarizing key successes and findings from the EPA-NIMHD Center pilot supplements. EPA will provide to the contractor results from research conducted by the Center grantees and other information that may guide how this document is formulated.

In order to write a report at the high level of quality needed, the effort will require staff with education backgrounds at both PhD and Master's degree levels with expertise in public and/or environmental health.

Staff at the PhD level will need to evaluate the important research results and their potential significance for achieving outcomes in the years to come. It may be necessary to utilize outside resources to evaluate the impact of the Centers. Staff at the Master's degree level will review grants reports, and other materials supplied by EPA, draft the summary, review comments and finalize the report.

The contractor shall:

a) Review materials provided by EPA and prepare a proposed draft outline for review by the EPA Project Officer.
b) Define the parameters for the report and help identify creative methods for reporting research findings and other information.
c) Where necessary, contact current and previous NIMHD Center grantees to collect required data and information.
d) Prepare a draft of the synthesis report for review by the EPA Project Officer based on the report outline.
e) Revise the draft report based on comments from the EPA Project Officer and develop the final report.

Task 4 Support the P3 Program

Task 4.1 Annual progress review meeting

Plan and implement an annual meeting for P3 grantees to present their projects. The contractor shall:

a) Arrange call to initiate P3 support efforts.
b) Serve as EPA and P3 exhibitor liaison leading up to, and at TechConnect.
c) Ensure that space allocated by TechConnect provides optimal layout for maximum P3 participant exposure and attendee flow.
d) Assist EPA in arranging activities to enhance P3 exhibitor experience.
e) Set up the space allocated by TechConnect with program signage (provided by EPA) and participate in festival. Also serve as contact point at the festival.
f) Conduct and collate post-event evaluations from P3 team participants. Evaluation text will be provided by EPA.

Task 4.2 2017 P3 Solicitation support

Stimulate national academic interest in the program to achieve a large pool of outstanding qualified grant applications for EPA to choose from to award Phase I grants.

a) The contractor shall send two email blasts to department chairs of colleges and universities throughout the U.S. announcing the 2017 P3 solicitation. Email blast language will be provided by EPA.

IV. ANTICIPATED DELIVERABLES

All products by the Contractor must be of high quality, written in a clear concise style, with a logical organization and presentation. Deliverables shall be provided to EPA in electronic formats compatible with EPA-supported software (e.g., MS Office 2010 (or later) spreadsheets and documents.

V. DELIVERABLES AND SCHEDULE

Task 1.	Initial conference call	3 days after award of Work Assignment
Task 2.	Work and Staffing Plan QAPP	20 days after award 1 weeks after award
Task 3.1	Participate in workgroup calls Proposed outline Collect materials from Centers Revised outline First Draft of report Second Draft of report Third Draft Laid out Final Review Draft Final Report	As arranged Within two weeks of receiving materials 4 weeks 2 weeks after all materials collected 6 weeks after outline approved Within 2 weeks of NCER approval and comments Within 2 weeks of NCER approval and comments Within 2 weeks of NCER approval and comments Three weeks after receiving NCER approval
Task 3.2.	Arrange call to initiate effort Participate in workgroup calls Proposed outline Collect materials from grantees Revised outline First Draft of report Second Draft of report Third Draft Laid out Final Review Draft Final Report	Within 2 weeks after award of Work Assignment As arranged Within two weeks of receiving materials 4 weeks 2 weeks after all materials collected 6 weeks after outline approved Within 2 weeks of NCER approval and comments Within 2 weeks of NCER approval and comments Within 2 weeks of NCER approval and comments Three weeks after receiving NCER approval
Task 3.3.	Arrange call to initiate effort Participate in workgroup calls Proposed outline Collect materials from grantees Revised outline First Draft of report Second Draft of report Third Draft Laid out Final Review Draft Final Report	Within 2 weeks after award of Work Assignment As arranged Within two weeks of receiving materials 4 weeks 2 weeks after all materials collected 6 weeks after outline approved Within 2 weeks of NCER approval and comments Within 2 weeks of NCER approval and comments Within 2 weeks of NCER approval and comments Three weeks after receiving NCER approval
Task 4.	Arrange call to initiate effort Subcontract/Register 50 exhibit spaces Liaise USASEF/EPA/P3 exhibitors Ensure optimal exhibit space layout	Within 2 weeks after award of Work Assignment Within 8 weeks of award of Work Assignment Continuous thru April USASEF Within 12 weeks of award of Work Assignment

	Enhance P3 exhibitor experience	Continuous thru April USASEF
	Support/meeting logistics/materials	March 2016
	Prepare Signage	April 2016
	Arrange exhibit space	April 2016
	Prepare post USASEF evaluations	May 2016
	Distribute eblast to universities	October and November 2016

Note: All days are calendar days.

VI. MANAGEMENT CONTROLS

1. All deliverables shall be reviewed for conformance to the requirements of this work assignment before being approved as final.
2. The contractor shall comply with other applicable requirements for final work assignment reports stipulated in contract.

VII. NOTICE REGARDING GUIDANCE PROVIDED UNDER THIS PROJECT

Guidance is strictly limited to technical and analytical support. The contractor shall not engage in activities of an inherent governmental nature such as the following:
(1) Formulation of Agency policy
(2) Selection of Agency priorities
(3) Development of Agency regulations

Should the contractor receive any instruction from an EPA staff person that the contractor ascertains to fall into any of these categories or goes beyond the scope of the contract or work assignment, the contractor shall immediately contact the PO, WAM or CO.

VIII. SPECIAL CONDITIONS AND ASSUMPTIONS

The contractor shall hold a conference call with the EPA WAM at the initiation of the work assignment, and shall provide a bi-weekly update to the WAM by telephone for the duration of the work assignment, in addition to the standard reporting requirements of the contract.

IX. EPA CONTACT INFORMATION

Copies of all correspondence pertaining to the performance of this work assignment shall be sent to the PO.

Work Assignment Manager (WAM):

Nica Louie
U.S. EPA/ORD/NCER
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460
Telephone: 202-564-7633

Alternate WAM:

Anne Sergeant
U.S. EPA/ORD/NCER
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460
Telephone: 202-564-6474

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 3-61

☐ Other ☒ Amendment Number: 000001

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-14-001	11/01/2013 To 10/31/2017	
	Base Option Period Number 3	

Contractor: ICF INCORPORATED, L.L.C.

Specify Section and paragraph of Contract SOW:

Purpose:
- ☐ Work Assignment
- ☒ Work Assignment Amendment
- ☐ Work Plan Approval
- ☐ Work Assignment Close-Out
- ☐ Incremental Funding

Period of Performance: From 11/01/2016 To 10/31/2017

Comments:
This request is for Additional Work With-In Scope so that the vendor may complete the current task(s) on the Work Assignment. The description of these Task(s) are attached.

☐ Superfund — Accounting and Appropriations Data — ☒ Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (*Max 2*) ☐

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
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4										
5										

Authorized Work Assignment Ceiling

Contract Period: 11/01/2013 To 10/31/2017 — Cost/Fee: — LOE:

This Action:

Total:

Work Plan / Cost Estimate Approvals

Contractor WP Dated: — Cost/Fee — LOE:

Cumulative Approved: — Cost/Fee — LOE:

Work Assignment Manager Name: Nica Louie (Signature) (Date)	Branch/Mail Code: Phone Number: 703-347-8125 FAX Number:
Project Officer Name: Joseph W. Hicks (Signature) (Date)	Branch/Mail Code: Phone Number: 202-564-1449 FAX Number:
Other Agency Official Name: (Signature) (Date)	Branch/Mail Code: Phone Number: FAX Number:
Contracting Official Name: William Yates (Signature) (Date)	Branch/Mail Code: Phone Number: 513-487-2055 FAX Number:

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 3-62

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-14-001	11/01/2013 To 10/31/2017 Base Option Period Number 3	In Vivo Point of Departure Dat

Contractor	Specify Section and paragraph of Contract SOW
ICF INCORPORATED, L.L.C.	C.1

Purpose:
- [X] Work Assignment
- [ ] Work Assignment Amendment
- [ ] Work Plan Approval
- [ ] Work Assignment Close-Out
- [ ] Incremental Funding

Period of Performance: From 11/01/2016 To 10/31/2017

Comments:

☐ Superfund — Accounting and Appropriations Data — [X] Non-Superfund

SFO (*Max 2*): ☐

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

Contract Period: 11/01/2013 To 10/31/2017 — Cost/Fee: — LOE:

This Action:

Total:

Work Plan / Cost Estimate Approvals

Contractor WP Dated: — Cost/Fee — LOE:

Cumulative Approved: — Cost/Fee — LOE:

Work Assignment Manager Name: Sandra Roberts (Signature) (Date)	Branch/Mail Code: Phone Number: 919-541-3850 FAX Number:
Project Officer Name: Melissa Revely-Wilson (Signature) (Date)	Branch/Mail Code: Phone Number: 919-541-0207 FAX Number:
Other Agency Official Name (Signature) (Date)	Branch/Mail Code: Phone Number: FAX Number:
Contracting Official Name: William Yates (Signature) (Date)	Branch/Mail Code: Phone Number: 513-487-2055 FAX Number:

PERFORMANCE WORK STATEMENT
CONTRACT NO. EP-C-14-001
WA 3-62

TITLE: Technical Support for the Development of an In Vivo Point of Departure Database

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Sections and Paragraphs of Contract SOW: C.1

PERIOD OF PERFORMANCE: CO approval/issuance through October 31, 2017

I. PURPOSE

The purpose of this Work Assignment (WA) is to provide services to the U.S. Environmental Protection Agency's (hereinafter, EPA) National Center for Environmental Assessment (NCEA) and National Center for Computational Toxicology (NCCT), within the Office of Research and Development (ORD). The specific purpose is to provide technical support for the development of a database of curated in vivo point of departure (POD) values for a diverse set of oral noncancer and cancer endpoints as identified in the contract performance work statement, Section C.1. The majority of work is expected to consist of study quality evaluation and dose-response analyses supporting the identification of study-level lowest-observed-adverse-effect level (LOAEL) values for many toxicity studies associated with several different chemicals. Data QA and data management will also be a part of the tasks in this WA.

II. BACKGROUND

Over the past four decades, EPA has made significant progress in protecting human health and the environment from the adverse effects of chemical exposures. The tens of thousands of chemicals in the environment, however, are overwhelming our ability to evaluate their safety using traditional approaches. Cognizant of this impediment, the release of the National Research Council's Report "Toxicity Testing in the 21st Century: A Vision and a Strategy" (NRC, 2007) initiated a broad-based movement in the toxicology community to reassess how toxicity testing and risk assessment are performed. Several studies have been conducted over the past five years that together may contribute first steps toward executing the shared vision, and these studies were recently assembled into a data-driven framework that invokes successive tiers of toxicity testing (Thomas et al., 2013).

In a collaborative effort between EPA's NCEA and NCCT, projects are currently under way with respect to the first tier of the aforementioned tiered framework. In one such project, the general approach is to develop a database that collates in vivo POD values in a semi-standardized way from multiple data sources. The database will ultimately be used in future proof-of-concept evaluations as the basis for comparison with POD values estimated using data from multiple high-throughput approaches/methods including physicochemical structure and in vitro assays. This WA supports the development of this in vivo POD database.

III. STATEMENT OF WORK

Task 1: Establish Communication

Within three (3) days of start date of this WA, the Contractor shall schedule a kick-off conference call (not to exceed 2 hours) with the EPA Work Assignment Manager (WAM) and appropriate contractor staff to clarify outstanding questions and confirm the schedule and specific tasks.

Task 2: Work Plan, Staffing Plan, and Quality Assurance Project Plan (QAPP)

The Contractor shall prepare a Technical Work Plan describing how the work outlined in this Performance Work Statement will be performed, including deliverables, a schedule, budget, and level of effort. The Contractor shall also prepare a Staffing Plan (submitted as part of the Work Plan) that shows assigned personnel by task and the qualifications of the proposed personnel. At a minimum, major contributors in this WA are expected to be Professional Level 4 or 3 and have expertise in the areas of toxicology and human health risk assessment. Personnel with additional training and certifications (e.g., DABT) are highly recommended. Contract staffing with previous experience in developing health assessment documents for the U.S. EPA and a thorough familiarity with EPA guidance utilized for performing health assessments is highly desired. Additionally, the contractor shall provide personnel who are highly proficient with the software tools Microsoft Access and Microsoft Excel. Additionally, personnel proficient in MySQL is preferred but not required.

The Contractor shall also develop a QAPP for approval by the WAM and Quality Assurance Manager. See these documents: "EPA Manual C/0 2105-P-01-0: EPA Quality Manual for Environmental Programs (QAPP)" and "EPA Requirements for Quality Assurance Project Plans (QA/R-5)." The QAPP shall be submitted simultaneously with the Work Plan for approval. The Contractor shall not perform any work on subsequent tasks under this PWS until the Work Plan and QAPP are reviewed and approved. If the WAM determines that the final Work and Staffing Plan is inadequate, the Contractor will have ten (10) days to submit substitute staff for review and approval by the WAM.

Task 3: Study Quality Evaluation

EPA will provide the Contractor with any additional decided upon format by which study data to be analyzed will be submitted. It will likely be outputted database files in the form of Microsoft Excel Comma Separated Values Files or standard Excel spreadsheets (one file per study) that will contain a study's design and treatment group information as well as the observed treatment-related effects. The edited/amended versions of these files will ultimately be reintegrated into the MYSQL version of ToxRefDB and eventually combined with data from other sources into an in vivo POD database. Attachment 2 previously submitted with the PWS for WA 1-62 is a README file that will assist the Contractor in the proper interpretation of the data and performing the tasks within this WA. Files of all studies (primarily in PDF format) will also be provided to the Contractor using a standardized file naming convention. TIFF, Word, and Word Perfect are other potential file formats the studies may be provided as.

In Task 3, the Contractor shall finalize the study quality evaluation for all studies identified as "open lit" or "unknown/unpublished" (roughly 608 total studies). Study quality shall be evaluated using the modified ToxRTool (Schneider et al., 2009) previously developed and piloted by the Contractor in WA 1-62. EPA and OECD guidelines can also be consulted for recommendations on the design and interpretation of toxicology experiments. The Contractor shall provide transparent documentation of the evaluation of "open lit" and "unknown/unpublished" study quality on a study-by-study basis via the "study_comment" field in the edited/amended database deliverables.

Task 4: Identification of Critical Effect(s) and Establishment of Study-Level Lowest-Observed-Adverse-Effect Level (LOAEL) Values

The noncancer effects listed in the "effect_type", "effect_target", and "effects_desc" fields have been previously determined to be treatment-related and statistically and/or biologically significant. An example of an effect type, target, and description would be pathology, liver, and hypertrophy, respectively. In Task 4, from all previously identified treatment-related effects, the Contractor shall use expert judgment (augmented by the "Determination of Critical Effects and Study Level NOAEL & LOAEL" and "Instructions for Critical Effect Determination for WA 1-62 Task 4" documents previously developed by the Contractor) to identify the critical effect(s) to establish study-level LOAEL values on a study-by-study basis for roughly 2,138 specific studies. The critical effect(s) used to identify the study-level LOAEL shall be denoted by "checking" the box of the Boolean (yes/no) "critical effect" field in the edited/amended database deliverables. "NULL" value entries for a given treatment group indicate that no treatment-related effects were observed. A brief rationale/narrative regarding the choice of the critical effect(s) and establishment of the study-level LOAEL value shall be provided in the "dose_comment" field on a study-by-study basis. Additionally, in the process of determining the critical effect(s) to establish study-level LOAEL values, any remarks on the treatment-relatedness of the observed effects (previously determined) should be documented in the "effect_comment" field.

For all multigeneration reproductive toxicity studies (denoted as "MGR") identified in the "study_type" field, treatment-related effects were further identified as either a "Parental", "Reproductive", or "Offspring" effect category. Thus, "Parental", "Reproductive", and "Offspring" study-level LOAEL values should be identified whenever applicable on a study-by-study basis. Similarly, for all prenatal developmental toxicity studies (denoted as "DEV") in the "study_type" field, treatment-related effects were further identified as either a "Maternal" or "Developmental" effect. Thus, "Maternal" and "Developmental" study-level LOAEL values should be identified whenever applicable on a study-by-study basis.

Although cancer effects are associated with some studies, study-level LOAEL values should not be identified based on cancer effects. However, dose-related incidence information [e.g., "at doses ≥ 100 mg/kg-day, hepatocellular adenomas (7/10 male rats") and carcinomas (3/10 male rats) were observed after 2-years of exposure] for any statistically or biologically significant tumor type should be captured in the "study_comment" field in the edited/amended database deliverable.

For additional information and guidance that may be useful in the completion of Tasks 3 and 4 of this WA, please refer to Knudsen et al. (2009) and Martin et al. (2009a, 2009b) (see Part X below).

IV. ANTICIPATED DELIVERABLES

As stated above, we anticipate that the primary deliverables will be edited/amended versions of the database files ultimately submitted with this WA. All products by the Contractor must be of high quality, written in a clear concise style, with a logical organization and presentation. The use of "redline" versions of the documents shall be employed throughout the process (when applicable). All documents shall be technically edited for format and grammar before being submitted to the WAM. Deliverables shall be provided to EPA in electronic formats compatible with EPA-supported software (e.g., Microsoft Excel, Word, and Access files).

V. DELIVERABLES AND SCHEDULE

Task 1. Initial Conference Call	3 days after award of Work Assignment
Task 2. Work Plan, Staffing Plan, and QAPP	15 days after award of Work Assignment

Task 3. Study Quality Evaluation (approximately 608 studies)	Monthly (to finalize work from WA 2-62, as studies are mostly completed) after approval of the Work Plan and QAPP
Task 4. Identification of Critical Effect(s) and Establishment of Study-Level Lowest-Observed-Adverse-Effect Level (LOAEL) Values (approximately 2,138 studies)	Monthly (as individual studies are completed) after approval of the Work Plan and QAPP

Note: All days are calendar days.

VI. MANAGEMENT CONTROLS

1. All deliverables shall be reviewed for conformance to the requirements of this work assignment before being approved as final.

2. The contractor shall comply with other applicable requirements for final work assignment reports stipulated in contract.

VII. NOTICE REGARDING GUIDANCE PROVIDED UNDER THIS PROJECT

Guidance is strictly limited to technical and analytical support. The contractor shall not engage in activities of an inherent governmental nature such as the following:

(1) Formulation of Agency policy
(2) Selection of Agency priorities
(3) Development of Agency regulations

Should the contractor receive any instruction from an EPA staff person that the contractor ascertains to fall into any of these categories or goes beyond the scope of the contract or work assignment, the contractor shall immediately contact the PO, WAM, or CO.

VIII. SPECIAL CONDITIONS AND ASSUMPTIONS

The contractor shall hold a conference call with the EPA WAM at the initiation of the work assignment, and provide regular updates on progress and any issues that need to be resolved to the WAM by telephone or by email, in addition to the standard reporting requirements of the contract. Any technical directions made during informal discussions shall be issued promptly by the EPA WAM in writing (to include email).

IX. EPA CONTACT INFORMATION

Copies of all correspondence pertaining to the performance of this work assignment shall be sent to the PO.

Work Assignment Manager (WAM):

Matthew Martin, Ph.D.
919-541-4104 (Phone)

919-541-1194 (Fax)
Martin.matt@epa.gov

Mailing Address:
U.S. Environmental Protection Agency
National Center for Computational Toxicology
109 T.W. Alexander Dr.
MD-D143-02
RTP, NC 27711

Alternate Work Assignment Manager (Alt. WAM):

Sandra Roberts
919-541-3850 (Phone)
919-541-1194 (Fax)
Roberts.sandra@epa.gov@epa.gov

Mailing Address:
U.S. Environmental Protection Agency
National Center for Computational Toxicology
109 T.W. Alexander Dr.
MD-D143-02
RTP, NC 27711

X. REFERENCES

Knudsen TB, Martin MT, Kavlock RJ, Judson RS, Dix DJ, Singh AV (2009). Profiling the activity of environmental chemicals in prenatal developmental toxicity studies using the U.S. EPA's ToxRefDB. Reprod. Toxicol. 28:209–219.

Martin MT, Judson RS, Reif DM, Kavlock RJ, Dix DJ (2009a). Profiling chemicals based on chronic toxicity results from the U.S. EPA ToxRef Database. Environ. Health Perspect. 117:392–399.

Martin MT, Mendez E, Corum DG, Judson RS, Kavlock RJ, Rotroff DM, Dix DJ (2009b). Profiling the reproductive toxicity of chemicals from multigeneration studies in the toxicity reference database. Toxicol. Sci. 110:181–190.

NRC (2007). Toxicity Testing in the 21st Century: A Vision and a Strategy. National Research Council of the National Academies, Washington, DC.

Schneider K, Schwarz M, Burkholder I, Kopp-Schneider A, Edler L, Kinsner-Ovaskainen A, Hartung T, Hoffmann S (2009). "ToxRTool", a new tool to assess the reliability of toxicological data. Toxicol Lett. 189:138–144.

Thomas RS, Philbert MA, Auerbach SS, Wetmore BA, Devito MJ, Cote I, Rowlands JC, Whelan MP, Hays SM, Andersen ME, Meek ME, Reiter LW, Lambert JC, Clewell HJ 3rd, Stephens ML, Zhao QJ, Wesselkamper SC, Flowers L, Carney EW, Pastoor TP, Petersen DD, Yauk CL, Nong A (2013). Incorporating new technologies into toxicity testing and risk assessment: moving from 21st century vision to a data-driven framework. Toxicol. Sci. 136:4–18.

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 3-62

☐ Other ☒ Amendment Number: 000001

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-14-001	11/01/2013 To 10/31/2017	In Vivo Point
	Base Option Period Number 3	

Contractor: ICF INCORPORATED, L.L.C.

Specify Section and paragraph of Contract SOW:

Purpose:
- ☐ Work Assignment
- ☒ Work Assignment Amendment
- ☐ Work Plan Approval
- ☐ Work Assignment Close-Out
- ☐ Incremental Funding

Period of Performance: From 11/01/2016 To 10/31/2017

Comments:
Remove Matthew Martin as Alt. COR - left agency. All other terms and conditions remain unchanged.

☐ Superfund — Accounting and Appropriations Data — ☒ Non-Superfund

SFO (*Max 2*) ☐

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

	Cost/Fee:	LOE:
Contract Period: 11/01/2013 To 10/31/2017		
This Action:		
Total:		

Work Plan / Cost Estimate Approvals

	Cost/Fee	LOE:
Contractor WP Dated:		
Cumulative Approved:		

Work Assignment Manager Name: Sandra Roberts (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	919-541-3850
	FAX Number:	
Project Officer Name: Melissa Revely-Wilson (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	919-541-0207
	FAX Number:	
Other Agency Official Name (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	
	FAX Number:	
Contracting Official Name: William Yates (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	513-487-2055
	FAX Number:	

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 3-68

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-14-001	11/01/2013 To 10/31/2017 Base Option Period Number 3	Tech Edit Revision Spprt RAF

Contractor: ICF INCORPORATED, L.L.C.

Specify Section and paragraph of Contract SOW: A. Assessment Issues and Documents

Purpose:
- [X] Work Assignment
- [ ] Work Assignment Amendment
- [ ] Work Plan Approval
- [ ] Work Assignment Close-Out
- [ ] Incremental Funding

Period of Performance: From 11/01/2016 To 10/31/2017

Comments:

☐ Superfund — Accounting and Appropriations Data — [X] Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (*Max 2*) ☐

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

	Cost/Fee	LOE
Contract Period: 11/01/2013 To 10/31/2017		
This Action:		
Total:		

Work Plan / Cost Estimate Approvals

	Cost/Fee	LOE
Contractor WP Dated:		
Cumulative Approved:		

Work Assignment Manager Name: Michael Broder (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	202-564-3393
	FAX Number:	
Project Officer Name: Melissa Revely-Wilson (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	919-541-0207
	FAX Number:	
Other Agency Official Name (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	
	FAX Number:	
Contracting Official Name: William Yates (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	513-487-2055
	FAX Number:	

TITLE: Technical Editing and Revision Support of Risk Assessment Forum Documents

Specify Section & Paragraph SOW: A. Assessment Issues and Documents

PERIOD OF PERFORMANCE: CO award to 10/31/17

A. **BACKGROUND**

Federal regulatory agencies often rely on risk assessments as a primary component in their decision-making process. To ensure that assessments are conducted in a consistent and transparent manner the Environmental Protection Agency (EPA) develops guidelines, guidance documents and "white papers" to provide a framework for analyzing data. EPA's Risk Assessment Forum (RAF) is charged with coordinating the development of Agency-wide guidelines and guidance documents that provide that framework. The principal audience for these products are EPA risk assessors and risk managers; however, these documents also provide clarity and transparency to the stakeholders and other interested parties, and are often cited by other regulatory entities.

B. PURPOSE

As noted above, guidelines and related products are among the most important products generated by the EPA. The intent of these products is to inform risk assessors how to acquire data and apply it to risk assessments, to promote consistency in Agency risk assessments and to inform stakeholders and other interested parties of EPA risk assessment policies and practices. As such, these documents need to be written in a clear and concise manner.

The first step in document revision and editing is monitoring discussions among the technical panel to identify changes to the document. Following those meetings the technical panel will revise the document and the document will be submitted to the Contractor for technical editing.

This work assignment will serve as a generic task with the intention that it will cover support for the revision and technical editing of several documents for which technical direction will be issued for each product. The technical direction accompanying each document will contain instructions specific to that product.

C. KNOWLEDGE AND SKILLS REQUIRED

Although much of the content has been provided, it is essential that the Contractor possess demonstrated experience in the production of quality EPA guidelines with an appropriate level of expertise in exposure science, human health and ecological risk assessment methods, to adequately critique and edit RAF documents for clarity and consistency, as well as providing grammatical editing. The Contractor shall be experienced with the use of Endnote database software and MS Word 2013 and 2016. The Contractor shall also be proficient in developing and populating basic databases using MS Access 2013 and 2016. The Contractor shall be competent in tracking meeting discussions and taking meeting notes. The level of expertise for each task will be commensurate with the technical direction.

D. TASKS

Task 1: Establish Communication

Within 3 days of start date of this WA, the Contractor shall schedule a conference call (not to exceed 1 hour) with the COR, workgroup members, and appropriate Contractor staff to clarify outstanding questions and confirm the schedule and specific tasks for the work assignment. Similarly, the Contractor shall initiate communication with the COR within three days of the issuance of any technical direction issued by the COR. The Contractor shall initiate additional communication with the COR should developments arise that will affect the conduct or schedule of the assignment.

Task 2: Work Plan and Staffing Plan

The Contractor shall prepare a Technical Work Plan describing how the work outlined in the technical direction under this Performance Work Statement will be performed, including deliverables, a schedule, budget, and level of effort. The Contractor shall also prepare a Staffing Plan, which shall be submitted as part of the Work Plan that shows assigned personnel by task and the qualifications of the proposed personnel.

Task 3. Tracking Meeting Discussions

The Contractor shall participate in meetings as stated in the technical direction; take meeting notes on recommended changes to the document; record the changes in the compiled comments from reviewers and incorporate those changes in the document. The Contractor shall update references, links, and hyperlinks consistent with the revisions per technical direction.

Task 4. Technical Editing

The Contractor shall review and edit the document addressing grammatical, syntax, and spelling errors that may exist in the document with specific attention to the items listed in the technical direction. The technical direction may also include associated activities such as tabulating reviewers' comments on draft documents. As stated in the technical direction, the Contractor shall establish or maintain a database of references/citations in Endnote software. The Contractor shall maintain ongoing communication with the COR to ensure quality and timely completion of the project.

Task 5. Compilation of Comments

As per technical direction, the Contractor shall compile comments received during review of the document and assemble the comments in a format per technical direction. As appropriate and in consultation with the COR, comments of a similar vein shall be consolidated.

Task 6. Delivery of the Final Product

The Contractor may deliver electronic versions (MS Word 2013 or as specified in the technical direction) of the edited document to the COR, alternate COR, and others designated in the technical direction including both clean and marked-up drafts: the latter shall be a revised document presented as a "track changes."

E. SCHEDULE AND DELIVERABLES

Product	Due Date
Task 1. Initial Conference Call	3 days after award
Task 2. Staffing Plan	Per contact requirements
Task 3. Attend and track meetings, taking notes. The Contractor shall update references, links, and hyperlinks consistent with the revisions per technical directions.	As specified in the technical direction
Task 4. Shall review and edit the document addressing grammatical, syntax, and spelling errors that may exist in the document with specific attention to the items listed in the technical direction laid out in the attachment.	As specified in the technical direction.
Task 5. Shall compile comments received during review of the document.	As specified in the technical direction.
Task 6. Shall deliver an electronic version (MS Word or as directed in the technical direction) of the draft document to the COR, alternate COR, and others designated in the technical direction including each in both clean and marked-up drafts: the latter shall be a revised document presented as a "track changes unless otherwise specified in the technical direction.	As specified in the technical direction.

F. Acceptance Criteria

Final products shall be produced by the Contractor upon the EPA WA COR's approval through written technical direction. The Contractor shall provide all materials written as part of these tasks to the EPA WA COR, as per work assignment, in electronic format. Electronic versions shall be in MS Word 2013, PowerPoint 2013 and Excel 2013 computer format unless otherwise specified in the technical direction.

G. MANAGEMENT CONTROLS:

Periodic meetings between the EPA and Contractor work assignment managers are encouraged to discuss any questions that may arise during performance or completion of this work assignment. At the EPA WA COR's discretion, these meetings may occur via teleconference or video conferences. The Contractor shall document these meetings and submit copies of this correspondence to the EPA WA COR.

The EPA WA COR may identify one or more EPA technical representatives for this work assignment. Interaction between the Contractor and any EPA technical representative(s) designated by the EPA WA COR is solely for the purpose of presenting and discussing the information, analyses, results, or presentations related to this work assignment. The interaction will be technical communication vice technical direction. Per the technical direction clause EPAAR 1552.237-71 of the contract, the EPA PO COR and the EPA WA COR or alternate EPA WA COR are the only representatives of the CO authorized to provide technical direction.

Per the technical direction clause, the CO and PO will be provided with copies of all technical direction.

H. CONFIDENTIALITY

Some of the information to be edited under this task may be internal information that is not ready for public distribution. The Contractor shall not discuss the contents of the document with anyone not specified as a participant in the document review process or its preparation.

VI. MANAGEMENT CONTROLS

1. All deliverables shall be reviewed for conformance to the requirements of this work assignment before being approved as final.

2. The Contractor shall comply with other applicable requirements for final work assignment reports stipulated in contract.

NOTICE REGARDING GUIDANCE PROVIDED UNDER THIS PROJECT

Guidance is strictly limited to technical and analytical support. The contractor shall not engage in activities of an inherent governmental nature such as the following:

(1) Formulation of Agency policy
(2) Selection of Agency priorities
(3) Development of Agency regulations

Should the contractor receive any instruction from an EPA staff person that the contractor ascertains to fall into any of these categories or goes beyond the scope of the contract or work assignment, the contractor shall immediately contact the PO , WAM or CO

SPECIAL CONDITIONS AND ASSUMPTIONS

The contractor shall hold a conference call with the EPA WAM at the initiation of the work assignment, and shall provide a bi-weekly update to the WAM by telephone for the duration of the work assignment, in addition to the standard reporting requirements of the contract.

EPA CONTACT INFORMATION

Copies of all correspondence pertaining to the performance of this work assignment shall be sent to the PO.

Work Assignment Manager (WAM):

Work Assignment COR
Michael W. Broder
Office of Science Advisor
U.S. EPA (8105-R)
Office of the Science Advisor
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460
Telephone: (202) 564-3393
Fax: (202) 564-2070

Alternate Work Assignment COR:
Michael Bender
Office of the Science Advisor
U.S. EPA (8105-R)
1200 Pennsylvania Ave., NW
Washington, DC, 20460
Telephone (202) 564-6829
Fax: (202) 564-2070

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 3-75

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-14-001	11/01/2013 To 10/31/2017 Base Option Period Number 3	Human Exposure Models

Contractor: ICF INCORPORATED, L.L.C.

Specify Section and paragraph of Contract SOW:

Purpose:
- [X] Work Assignment
- [ ] Work Assignment Amendment
- [ ] Work Plan Approval
- [ ] Work Assignment Close-Out
- [ ] Incremental Funding

Period of Performance: From 11/01/2016 To 10/31/2017

Comments:
WA 3-75 (Option Period 3): WA Continuation from 2-75 (ICF). Identification and adaptation of human exposure models to improve exposure factors in life cycle analysis applied to products and articles. WACOR: Dan Vallero. ALT WAM: Peter Egeghy.

☐ Superfund — Accounting and Appropriations Data — [X] Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (*Max 2*): ☐

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

	Cost/Fee	LOE
Contract Period: 11/01/2013 To 10/31/2017		0
This Action:		3,845
Total:		3,845

Work Plan / Cost Estimate Approvals

	Cost/Fee	LOE
Contractor WP Dated:		
Cumulative Approved:		

Work Assignment Manager Name: Daniel Vallero (Signature) (Date)	Branch/Mail Code: Phone Number: 919-541-3306 FAX Number:
Project Officer Name: Melissa Revely-Wilson (Signature) (Date)	Branch/Mail Code: Phone Number: 919-541-0207 FAX Number:
Other Agency Official Name: (Signature) (Date)	Branch/Mail Code: Phone Number: FAX Number:
Contracting Official Name: William Yates (Signature) (Date)	Branch/Mail Code: Phone Number: 513-487-2055 FAX Number:

PERFORMANCE WORK STATEMENT
CONTRACT NO. EP-C-14-001
WA – 3-75

TITLE: Identification and adaptation of human exposure models to improve exposure factors in life cycle analysis applied to products and articles

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PERIOD OF PERFORMANCE: 11/1/2016– 10/31, 2017

Specify Section & Paragraph SOW: (select all that apply)
A. Assessment Issues and Documents
5. Integrated Science Assessments
B. Risk Assessment Methods Research and Development
F. Information Management
G. Literature Search
H. Physiologically-Based Pharmacokinetic (PBPK) Model Technical Support

I. PURPOSE

The purpose of this Work Assignment (WA) is to provide services to the U.S. Environmental Protection Agency's (hereinafter EPA or Agency) Human Exposure and Atmospheric Sciences Division of the National Exposure Research Laboratory, Office of Research and Development (ORD).

II. BACKGROUND

The EPA's Chemical Safety for Sustainability research program has been developing new ways to prioritize the chemicals that are ingredients of products and articles. This prioritization has addressed both the toxicity potential (i.e. ToxCast) and exposure potential (i.e. ExpoCast). Together, these will be the basis for improved methods and approaches for risk prioritization of chemicals as early as possible, with the objective of identifying chemicals before they reach the marketplace or before they are ingredients in products wherein the use would lead to unacceptable exposures. Within modern society, exposure to a wide range of chemicals through our daily habits and routines is ubiquitous and largely unavoidable. The initial focus to estimate exposure to chemicals in products used in microenvironments (μE) necessitates a "systems" model to delineate data needs arising from numerous knowledge bases to integrate product formulations, purchasing and use activities, and human activities.

Evaluating chemical safety and sustainability over the life cycle of chemicals requires drawing upon the various data streams and impact assessment tools from the life cycle assessment (LCA) field, along with improved exposure models that rapidly and reliably characterize exposures and human health impacts of chemicals from direct and indirect exposure pathways, which vary across their full life cycle. LCA has proven to be a valuable tool for systematically comparing processes and products; however, exposure assessment has almost exclusively been devoted to far-field scenarios. Integration of human exposure modeling of near-field scenarios into LCA will require bridging the scientific and technical gaps that currently prevent the harmonious use of the best available methods and tools from both fields. A critical linkage is the development of a modeling system that makes use of existing stochastic and mechanistic human exposure models and will readily link to inputs and tools from the front-end life cycle inventory (LCI) and LCA modules; especially by enhancing the exposure factor in the calculation of the human health characterization factor.

The human exposure modeling elements of the overall research project will include the evaluation of existing model systems and appropriate adaptation of models to life cycle stages. The following life cycle stages are of particular interest in this effort, in order of priority:

- Residential/general population product use (near field exposure pathways)
- Occupational (professional) product use (near-field exposure pathways)
- Product end-of-life (recycling, reuse, disposal for near- and far-field exposure pathways)
- Product manufacturing (far-field and near-field exposure pathways)
- Chemical manufacturing (far-field and near-field exposure pathways)

Initial research efforts will focus on adapting and integrating near-field residential and general population exposure models into the life cycle framework, and extension of the models to near-field occupational (professional) product use. Evaluation, selection, and adaptation of end-of-life and occupational manufacturing models and modeling approaches is envisioned as a longer-term goal of this effort. Potential collaborations with NIOSH or other relevant organizations for occupational manufacturing exposure modeling will be explored.

The key expectation of this research is more reliable and better human health characterization factors (CFs) through enhancement of exposure metrics within the CF calculation. For residential (and professional) product use, the research builds directly upon recent advances in exposure-based chemical prioritization, ExpoCast, and SHEDS-HT (Stochastic Human Exposure and Dose Simulation, High-Throughput model), and will complement the CSS Rapid Exposure & Dosimetry Project. In particular, the research will leverage the knowledge gained through application of SHEDS-HT to provide higher-throughput estimates of exposure to chemicals in consumer products and articles, based on product chemical function and composition databases (e.g., CPcat and CPCPdb, respectively). The LCI and LCA approaches will benefit from evaluation tools for sustainable manufacturing of chemicals (e.g., GREENSCOPE) for providing specific information at a sub-process level for LCI generation.

Over the FY15-16 time period, SHEDS-HT will be adapted for application in a life cycle inventory and assessment framework. This includes improved time-location-activity diary and dietary algorithms and modification of SHEDS-HT modules to support additional pertinent near- and far-field exposure scenarios. In the longer time frame, near-field model results will be combined with information from other models for chemical/product manufacturing, use and disposal and fate and transport. Moreover, the human exposure modeling system will be developed to be flexible enough to accommodate the LCI and other LCA inputs, scenarios or processes. The project will also include various means of incorporating exposure information into characterization factors, e.g. adaptation of intake fractions, especially the product intake fraction (PiF), which can be combined with toxicity factors, e.g. ToxCast activity concentrations.

Scenario development is an important part of this effort and will be used to define and guide human exposure modeling system development. The system will represent far-field and near-field exposure scenarios. Existing models, especially USEtox, show promise in informing far-field aspects of each life cycle, including the end-of-life outputs. Likewise, SHEDS-HT may be a starting point for near-field models, beginning with residential product and article use and possible adaptation to professional product use. However, other models may be considered and adapted as appropriate. As such, literature reviews will be conducted to determine the relevance and quality of models and databases available, especially for the non-residential scenarios and for end-of-life aspects of these and other LCA stages.

In addition, to simulate different exposure and dose scenarios for chemicals across life-cycle stages, it is important also to consider the differences in the physiologic and pharmacokinetic factors for effected individuals at various life-stages. PBPK models have the capability to incorporate these physiological (e.g.,

body weight, fat percentage) and pharmacokinetic (e.g., metabolism rate, enzyme levels) variations in a study population. We plan to link probabilistic models of inter-individual variation in exposure and dosimetry using a modular exposure-to-dose approach to investigate the internal doses throughout the life-cycle. At this time it remains unknown whether this can be accomplished through a simple adaptation of an existing algorithm or will require development of a de novo approach. For modeling these linkages and doses, initially we will consider selecting chemicals such as flame retardants or other SVOCs in building materials in a relevant PBPK model for the human exposure modeling system. In particular, we may utilize the GastroPlus software tool and other PBPK related information from internal and external EPA collaborators during the development of the task-specific PBPK models. The goal of the PBPK modeling is to provide more rapid dose estimates across wider ranges of chemical space using widely available chemical and physiological parameters for relevant populations, life cycle stages, and time frames.

An overall goal of the research supported in part by this work assignment is an initial user interface to allow beta testing of a full modeling framework by the potential stakeholders. The model sensitivities and uncertainties will be assessed for each integrated modeling framework. Finally, several forms of model evaluation activities will be performed to ascertain the confidence in the model predictions. Individual modules of the modeling system can be evaluated independently (e.g., scenario definitions, emissions, concentrations, exposures), and overall model performance of the system can be evaluated methodically using biomonitoring data that is currently available (e.g., NHANES) or yet to be collected (e.g., by NIEHS/EPA Sister's Study Pilot project, Duke University's anticipated NIEHS-sponsored SVOC exposure and obesogens project). The biomarker data from such sources will be analyzed either directly or interpreted via reverse toxicokinetics (RTK) semi-empirical modeling methods.

This research project integrates emerging scientific information and tools from the LCA and chemical exposure and dose modeling areas. In particular, the integrated LCA/Exposure Modeling framework will provide the capability to rapidly assess environmental and human exposures to many chemicals and products over the life cycle of chemicals, to support the sustainability goals of CSS and other ORD integrated trans-disciplinary research areas. After environmental and human exposure assessments, the user will be able to identify the main life cycle stages that are influencing the evaluation results. The exposure and dose modeling tools will allow more rapid, flexible and reliable prediction of human exposures and doses for chemicals of interest to CSS within an enhanced LCA framework. The LCA exposure tool will be modular, which will facilitate further integration with ecological and hazard databases by separating inputs, model algorithms, and outputs of variability, sensitivity and uncertainty associated with the predictions.

III. STATEMENT OF WORK

Task 1: Human Behavior Components of Human Exposure Model (HEM)

Recent research efforts at the EPA have focused on the modeling of human activity and behavior patterns, specifically with respect to behaviors which dictate the use of consumer products, using agent based modeling (ABM) methods. Under the direction of the WA-COR, the Contractor will take existing Python code which shows proof of concept of this method, and develop working R code which implements the method (i.e., the use of ABM to model human behaviors), and creates the independent module to be used in the HEM software to model human behavior.

Deliverable: ABM/Human behavior working module (i.e., R code), and appropriate documentation.

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The HEM must have the capability to model longitudinal exposures via different pathway and routes. To this end, the contractor will develop and implement a longitudinal exposure module. This module will use as its basis the exposure scenario algorithm functions in SHEDS-HT, and take as inputs longitudinal patterns of consumer product use for individuals. The Contractor will develop a proposed approach after receiving initial technical guidance from the WA-COR. The proposed approach will include methods for addressing design issues identified by the WA-COR, including but not limited to implementing the SHEDS-HT fugacity model in a longitudinal manner, storing of longitudinal media concentrations, handling of carry-over exposures, handling of dermal removal process, and tracking of dermal loadings and pathway-specific exposures. The WA-COR will approve the proposed approach, upon which the Contractor will implement the method in R Code and complete a final memo describing the approach and code.

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Completed task	5 work days after receiving EPA comments
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(2) Selection of Agency priorities
(3) Development of Agency regulations

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IX. EPA CONTACT INFORMATION

Contracting Officer Representative: Daniel A. Vallero, PhD, NERL/HEASD, vallero.daniel@epa.gov, 919-541-3306

Alternate COR: Peter P. Egeghy, PhD, NERL/HEASD, egeghy.peter@epa.gov, 919-541-4103

Appendix A

Quality Assurance Instructions for Contractors Citing Secondary Data

Section 515 of the Treasury and General Government Appropriations Act for fiscal year 2001 directed the Office of Management and Budget (OMB) to issue guidelines to all Federal agencies to ensure and maximize the quality, objectivity, utility, and integrity of the information they disseminate. This law and the OMB guidance subsequently issued in 67 FR 8452 (02/22/02) underscore the need for EPA/NCEA to assess the quality and credibility of the secondary research information cited in its assessment documents.

Secondary research information is defined as information that was originally produced for one purpose but is now being recompiled or reassessed for a different purpose. Secondary research information usually originates from such primary sources as journal articles, books, government and industry reports, databases, and models. The set of processes that follows serves as a guide to evaluate the strength of secondary data gathered from these primary sources.

The Contractors must list the sources for the references cited in his/her document chapters or sections. The source list will include but not be limited to the names of any commercially available or local databases searched by computer or by hand, the search terms and search strategy used, and the time period of the search. List any print sources like books or journal articles which provided references. List any sources of raw data.

After fully reporting all of the reference sources, identify the most relevant information or key studies among the references you cite and critically evaluate them. Key studies are those most crucial or pivotal to answer the research questions for the project. The key study may have positive or negative results and may even be all that is currently available on the research topic, but the key study is integral to any discussion of the topic. Sometimes, the key study is not recognizable until all of the literature is gathered and evaluated. Key studies should exhibit at least most of the general attributes defined below:

FOCUS: the work not only addresses the area of inquiry under consideration but also contributes to its understanding;
VERIFY: the work is consistent with accepted knowledge in the field or, if not, the new or varying information is documented within the work; the work fits within the context of the literature and is intellectually honest and authentic;
INTEGRITY: Is the work structurally sound? In a piece of research, is the design or research rationale logical and appropriate?
RIGOR: the work is important, meaningful, and non-trivial relative to the field and exhibits sufficient depth of intellect rather than superficial or simplistic reasoning;
UTILITY: the work is useful and professionally relevant; it makes a contribution to the field in terms of the practitioners' understanding or decision-making on the topic.
CLARITY: Is it written clearly and appropriately for the nature of the study?

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 3-75

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-14-001	11/01/2013 To 10/31/2017 Base Option Period Number 3	Human Exposure Models

Contractor: ICF INCORPORATED, L.L.C.

Specify Section and paragraph of Contract SOW:

Purpose:
- [X] Work Assignment
- [ ] Work Assignment Amendment
- [ ] Work Plan Approval
- [ ] Work Assignment Close-Out
- [ ] Incremental Funding

Period of Performance: From 11/01/2016 To 10/31/2017

Comments:
WA 3-75 (Option Period 3): WA Continuation from 2-75 (ICF). Identification and adaptation of human exposure models to improve exposure factors in life cycle analysis applied to products and articles. WACOR: Dan Vallero. ALT WAM: Peter Egeghy.

☐ Superfund — Accounting and Appropriations Data — [X] Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (*Max 2*): ☐

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

	Cost/Fee	LOE
Contract Period: 11/01/2013 To 10/31/2017		0
This Action:		3,845
Total:		3,845

Work Plan / Cost Estimate Approvals

	Cost/Fee	LOE
Contractor WP Dated:		
Cumulative Approved:		

Work Assignment Manager Name: Daniel Vallero (Signature) (Date)	Branch/Mail Code: Phone Number: 919-541-3306 FAX Number:
Project Officer Name: Melissa Revely-Wilson (Signature) (Date)	Branch/Mail Code: Phone Number: 919-541-0207 FAX Number:
Other Agency Official Name: (Signature) (Date)	Branch/Mail Code: Phone Number: FAX Number:
Contracting Official Name: William Yates (Signature) (Date)	Branch/Mail Code: Phone Number: 513-487-2055 FAX Number:

PERFORMANCE WORK STATEMENT
CONTRACT NO. EP-C-14-001
WA – 3-75

TITLE: Identification and adaptation of human exposure models to improve exposure factors in life cycle analysis applied to products and articles

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PERIOD OF PERFORMANCE: 11/1/2016– 10/31, 2017

Specify Section & Paragraph SOW: (select all that apply)
A. Assessment Issues and Documents
5. Integrated Science Assessments
B. Risk Assessment Methods Research and Development
F. Information Management
G. Literature Search
H. Physiologically-Based Pharmacokinetic (PBPK) Model Technical Support

I. PURPOSE

The purpose of this Work Assignment (WA) is to provide services to the U.S. Environmental Protection Agency's (hereinafter EPA or Agency) Human Exposure and Atmospheric Sciences Division of the National Exposure Research Laboratory, Office of Research and Development (ORD).

II. BACKGROUND

The EPA's Chemical Safety for Sustainability research program has been developing new ways to prioritize the chemicals that are ingredients of products and articles. This prioritization has addressed both the toxicity potential (i.e. ToxCast) and exposure potential (i.e. ExpoCast). Together, these will be the basis for improved methods and approaches for risk prioritization of chemicals as early as possible, with the objective of identifying chemicals before they reach the marketplace or before they are ingredients in products wherein the use would lead to unacceptable exposures. Within modern society, exposure to a wide range of chemicals through our daily habits and routines is ubiquitous and largely unavoidable. The initial focus to estimate exposure to chemicals in products used in microenvironments (μE) necessitates a "systems" model to delineate data needs arising from numerous knowledge bases to integrate product formulations, purchasing and use activities, and human activities.

Evaluating chemical safety and sustainability over the life cycle of chemicals requires drawing upon the various data streams and impact assessment tools from the life cycle assessment (LCA) field, along with improved exposure models that rapidly and reliably characterize exposures and human health impacts of chemicals from direct and indirect exposure pathways, which vary across their full life cycle. LCA has proven to be a valuable tool for systematically comparing processes and products; however, exposure assessment has almost exclusively been devoted to far-field scenarios. Integration of human exposure modeling of near-field scenarios into LCA will require bridging the scientific and technical gaps that currently prevent the harmonious use of the best available methods and tools from both fields. A critical linkage is the development of a modeling system that makes use of existing stochastic and mechanistic human exposure models and will readily link to inputs and tools from the front-end life cycle inventory (LCI) and LCA modules; especially by enhancing the exposure factor in the calculation of the human health characterization factor.

The human exposure modeling elements of the overall research project will include the evaluation of existing model systems and appropriate adaptation of models to life cycle stages. The following life cycle stages are of particular interest in this effort, in order of priority:

- Residential/general population product use (near field exposure pathways)
- Occupational (professional) product use (near-field exposure pathways)
- Product end-of-life (recycling, reuse, disposal for near- and far-field exposure pathways)
- Product manufacturing (far-field and near-field exposure pathways)
- Chemical manufacturing (far-field and near-field exposure pathways)

Initial research efforts will focus on adapting and integrating near-field residential and general population exposure models into the life cycle framework, and extension of the models to near-field occupational (professional) product use. Evaluation, selection, and adaptation of end-of-life and occupational manufacturing models and modeling approaches is envisioned as a longer-term goal of this effort. Potential collaborations with NIOSH or other relevant organizations for occupational manufacturing exposure modeling will be explored.

The key expectation of this research is more reliable and better human health characterization factors (CFs) through enhancement of exposure metrics within the CF calculation. For residential (and professional) product use, the research builds directly upon recent advances in exposure-based chemical prioritization, ExpoCast, and SHEDS-HT (Stochastic Human Exposure and Dose Simulation, High-Throughput model), and will complement the CSS Rapid Exposure & Dosimetry Project. In particular, the research will leverage the knowledge gained through application of SHEDS-HT to provide higher-throughput estimates of exposure to chemicals in consumer products and articles, based on product chemical function and composition databases (e.g., CPcat and CPCPdb, respectively). The LCI and LCA approaches will benefit from evaluation tools for sustainable manufacturing of chemicals (e.g., GREENSCOPE) for providing specific information at a sub-process level for LCI generation.

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III. STATEMENT OF WORK

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Deliverable: ABM/Human behavior working module (i.e., R code), and appropriate documentation.

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Alternate COR: Peter P. Egeghy, PhD, NERL/HEASD, egeghy.peter@epa.gov, 919-541-4103

Appendix A

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EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 3-77

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-14-001	11/01/2013 To 10/31/2017	Standards for Pathogens
	Base Option Period Number 3	

Contractor	Specify Section and paragraph of Contract SOW
ICF INCORPORATED, L.L.C.	III.D, III.E.1, III.G

Purpose:
- [X] Work Assignment
- [ ] Work Assignment Amendment
- [ ] Work Plan Approval
- [ ] Work Assignment Close-Out
- [ ] Incremental Funding

Period of Performance: From 11/01/2016 To 10/31/2017

Comments:

☐ Superfund — Accounting and Appropriations Data — [X] Non-Superfund

SFO (*Max 2*): ☐

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
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5										

Authorized Work Assignment Ceiling

	Cost/Fee:	LOE:
Contract Period: 11/01/2013 To 10/31/2017		
This Action:		
Total:		

Work Plan / Cost Estimate Approvals

	Cost/Fee	LOE:
Contractor WP Dated:		
Cumulative Approved:		

Work Assignment Manager Name: Gary Russo (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	202-566-1335
	FAX Number:	
Project Officer Name: Melissa Revely-Wilson (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	919-541-0207
	FAX Number:	
Other Agency Official Name (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	
	FAX Number:	
Contracting Official Name: William Yates (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	513-487-2055
	FAX Number:	

PERFORMANCE WORK STATEMENT
ICF CONTRACT EP-C-14-001
WORK ASSIGNMENT 3-77

Title: Secondary Contact Water Quality Standards for Pathogens

Work Assignment Manager (WAM): Gary Russo (Mail Code 4305T)
Standards and Health Protection Division
Office of Water, Office of Science and Technology
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460
Phone (202) 566-1335
E-mail: russo.gary@epa.gov

Alternate WAM: Shari Barash (Mail Code 4305T)
Standards and Health Protection Division
Office of Water, Office of Science and Technology
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460
Phone (202) 566-0996
E-mail: barash.shari@epa.gov

Period of Performance: November 1, 2016 through October 31, 2017

Contractor SOW: III.D, III.E.1, III.G

CBI: No confidential business information will be needed for this work assignment.

Background:

EPA's bacteriological water quality criteria under section 304(a) of the Clean Water Act (CWA) address water quality standards for "primary contact" recreational uses and do not significantly address "secondary contact" recreational uses. Primary contact recreation is typically defined as water-based recreational activities that could be expected to result in the ingestion of or immersion in water such as swimming, water skiing, or surfing. Secondary contact recreation is typically defined as water-based recreational activities where contact with the water is either incidental or accidental, and the probability of ingesting appreciable quantities of water is minimal.

Current EPA policy allows States, tribes and territories to adopt bacteriological criteria for secondary contact uses that are less stringent than criteria for primary contact uses. The

justification for less stringent secondary contact criteria is based on the assumption that secondary contact activities are associated with exposure to fewer pathogenic organisms. It is believed that a higher concentration of pathogens in water is counterbalanced by a lower potential exposure to those pathogens, resulting in the same risk of illness in secondary recreational activities as risks associated with primary recreational activities. However, the potential for pathogen exposure during different recreational activities is not well characterized, and there is currently no scientific consensus on whether or not they are in fact associated with different risks of illness (differential risk).

Although there is a body of scientific literature addressing the risk of illness associated with various water-based recreational activities, the relationships between different activities, water quality, and health risks are not well understood. The wide ranges of existing studies often have ambiguous results or support conflicting conclusions. Such ambiguity and/or disagreement may be due to a variety of reasons, including differences in the questions being addressed, differences, biases and/or flaws in the way the studies were designed or conducted, differences in interpretation of the study results, or simply due to chance.

The purpose of this project is to examine the evidence for or against differential risk by conducting a systematic review. A systematic review is a specific type of literature review that focuses on a specific research question and tries to identify, appraise, select and synthesize all high quality research and evidence relevant to that question. The overall goal of a systematic review is to provide an objective and transparent synthesis of research results that minimizes bias. The systematic review will provide an up-to-date, state-of-the-art evaluation of the current scientific knowledge of the health risks associated with different water-based recreational activities in water contaminated by fecal material. The results and conclusions of the systematic review will be used to inform EPA policies and decisions associated with recreational water quality standards for the protection of public health.

The majority of the work for this project has already been performed and deliverables were already provided in conjunction with previous work assignments on contract EP-C-11-005 work assignments 1-10, 2-10, 3-10, and 4-10, and contract EP-C-14-001 work assignment 2-77. The purpose of this work assignment is to complete the project.

Performance Work Statement (PWS):

The scope of work in this PWS will fall under the following tasks:

Task 1 – Work plan, quality assurance, and monthly progress reports

Task Area 1.1 - Work plan

The contractor shall develop a work plan to address all tasks in the PWS. The work plan shall

include a schedule, staffing plan, level of effort (LOE), and cost estimate for each task, the contractor's key assumptions on which staffing plan and budget are based, and qualifications of proposed staff. If one or more subcontractor(s) are proposed and they are outside the metropolitan DC area, the contractor shall include information on plans to manage work and contract costs. The number and professional level of hours charged and total dollars for each task will be provided. Other costs greater than $100.00 shall be itemized.

- Deliverable – Work plan.
- Deadline – Fifteen (15) calendar days after receipt of work assignment

Task Area 1.2 - Quality assurance

Work assignments 1-10, 2-10, 3-10, and 4-10 under contract EP-C-11-005, and work assignment 2-77 under contract EP-C-14-001 required the use of existing data. Consistent with the Agency's quality assurance (QA) requirements, the contractor developed a contract-level quality assurance project plan (QAPP) and project-level QAPP to assure the quality of the existing data or any other types of data used in these work assignments. The contractor addressed the project-specific QA requirements in the previous work plans and monthly progress reports following Attachment 1 entitled: "QAPP requirements for projects using existing data." The QAPPs were approved by the EPA before activities using existing data began. In addition to the project-specific QAPP, the contractor developed a systematic review protocol that contained QA and quality control (QC) procedures for implementing the systematic review. **The contractor shall continue to implement all QA and QC procedures specified in the contract-level QAPP, project-level QAPP, and systematic review protocol for all work performed under this PWS.**

Upon completion of the systematic review, the contractor shall complete the EPA Office of Water Information Quality Guidelines checklist and supporting narrative (see Attachment 2).

- Deliverable – Completed Information Quality Guidelines checklist
- Deadline – Seven (7) calendar days following technical direction from EPA WAM.

Task Area 1.3 - Monthly Progress Reports

The contractor shall provide progress and financial reports to the EPA WAM each month. The contractor shall also provide any information related to the execution of this PWS whenever requested by the EPA WAM. The progress report shall indicate, in a separate QA/QC section, whether QA/QC issues have been identified and how they will be resolved. If significant QA/QC issues are encountered, the contractor shall contact the EPA WAM immediately to discuss the issue. If work ceases because of QA/QC issues, the contractor shall not resume work

until receiving written approval from the EPA WAM. Monthly financial reports shall at minimum include a table with the invoice LOE and costs for each task and task area in this PWS.

Task 2 – Finalize and publish systematic review

Task Area 2.1 - Finalize draft manuscript

The contractor shall finalize the draft manuscript developed during the previous work assignment for submission to a scientific journal. The manuscript shall be organized thoughtfully, written concisely, grammatically correct, academically rigorous, contain high quality tables and figures when appropriate, and formatted for the journal being targeted. The contractor shall develop the manuscript in a way that provides for efficient reformatting for submission to other scientific journals if needed. The contractor shall work closely with the EPA WAM and discuss all significant decisions and options while developing the manuscript.

- Deliverable – Final manuscript.
- Deadline – Thirty (30) days after receiving direction from the EPA WAM to begin finalizing the draft manuscript.

Task Area 2.2 - Response to reviewer comments

After EPA submits the manuscript to the publisher of the scientific journal, the publisher may request revisions to the manuscript in response to reviewer comments. If the publisher requests revisions to the manuscript in response to reviewer comments, the contractor shall work closely with the EPA WAM to develop point-by-point written responses to the reviewer comments for submission to the journal editor. The contractor shall also prepare the Information Quality Guidelines Checklist necessary for products that EPA disseminates to the public under EPA's Information Quality Guidelines. The contractor shall work closely with the EPA WAM and discuss all significant decisions and options while developing the response to reviewer comments.

- Deliverable – Response to comments document and Information Quality Guidelines Checklist.
- Deadline – Fifteen (15) days after manuscript revisions are completed and the contractor receives written instruction from the EPA WAM to begin development of response to comments.

Task Area 2.3 – Manuscript revisions in response to peer-review

After developing responses to reviewer comments, the contractor shall work closely with the EPA WAM to determine the appropriate manuscript revisions. After the EPA WAM determines

the appropriate manuscript revisions, the contractor shall revise the manuscript in response to the reviewer comments as instructed by the EPA WAM. The contractor shall only make those revisions directed by the EPA WAM. The contractor shall conform to the same standards of quality when revising the manuscript as specified above for finalizing the manuscript. The manuscript shall be organized thoughtfully, written concisely, grammatically correct, academically rigorous, contain high quality tables and figures when appropriate, and formatted for the journal being targeted. The contractor shall develop the manuscript in a way that provides for efficient reformatting for submission to other scientific journals if needed. The contractor shall work closely with the EPA WAM and discuss all significant decisions and options while finalizing the manuscript.

- Deliverable – Final manuscript.
- Deadline – Thirty (30) days after contractor completes responses to reviewer comments and receives instructions from EPA WAM to begin manuscript revisions.

Task Area 3 - General Project Support

Task Area 3.1 - Prepare briefing materials and other supporting documents pertaining to the systematic review

Briefing materials and other supporting documents will be needed during the systematic review development process and after the review is published. The contractor shall aid in the development of any materials or presentations for these purposes. This may include but is not limited to preparing interim project updates and other materials for internal and external audiences as requested by the EPA WAM, briefing documents, PowerPoint presentations, and other supporting documents as needed. The contractor may be requested by the EPA WAM to participate in and/or conduct briefings or participate in seminars or talks related to the systematic review.

- Deliverable – Requested materials and supporting documents.
- Deadline – As mutually agreed upon by the EPA WAM and contractor

Task Area 3.2 - Support options development and analyses for potential changes to EPA policies related to bacteriological water quality standards.

As the results and conclusions of the systematic review become clear, the EPA may want to consider alternative policies related to bacteriological water quality standards. The contractor shall aid in the development of potential alternative policy options. These activities may include, ,but are not limited to, performing additional research and analysis of existing scientific data and

information, analysis of the potential public health outcomes resulting from policy modifications, and the analysis of water quality standard implementation implications associated with the adoption of alternative bacteriological water quality standards. The contractor may be requested to participate in and/or conduct briefings or other presentations related to this work.

- Deliverable – Requested materials.
- Deadline – As mutually agreed upon by the EPA WAM and contractor

Travel:

Travel may be needed as deemed necessary by the EPA WAM. No contractor travel outside of the Washington, D.C. metro area is required.

Knowledge and Skills Required:

The contractor shall have the necessary scientific knowledge and expertise to develop the aforementioned materials in this PWS that are high quality and use state-of-the-art methods. Specifically, the contractor shall have experience designing, performing, and publishing primary scientific research evaluating the health effects of environmental pollution, as well as experience designing, performing, and publishing systematic- and meta-analyses of such studies. The contractor shall have expertise in epidemiological studies that evaluate microbiological water pollution using fecal indicator organisms. The contractor shall be proficient in advanced state-of-the-art statistical methods typically used to analyze epidemiological studies and perform meta-analyses. The contractor should also be competent in analytical methods used to monitor microbial water pollution (including molecular techniques), the determination of human exposure to environmental contaminant sources, and disease endpoints related to microbial exposure through contact with water.

General Requirements of the Work Assignment and Schedule:

Due Dates

The contractor shall mutually acceptable due dates with EPA WAM. The contractor shall notify the EPA WAM in advance, if a due date will not be met and negotiate a mutually acceptable revised due date.

Delays

The contractor shall provide sufficient qualified man-power to ensure there are no avoidable delays. If a delay outside the control of the contractor is unavoidable, the contractor shall immediately notify the EPA WAM and negotiate a mutually acceptable revised schedule.

Draft Documents

The contractor shall submit draft or interim work products requested by the EPA WAM. Draft or interim work products shall be prepared in an electronic format compatible with Microsoft Office 2013 and Endnote X. The EPA WAM will provide the contractor with comments on draft work products in electronic format. Work products shall be deemed draft until designated as final by the EPA WAM.

Final Documents

The contractor shall submit final documents electronically to the EPA WAM.

Meetings, Conferences, Training Events, Award Ceremonies and Receptions:

All appropriate clearances and approvals required by Agency policy in support of any and all conference related activities and expenses, including support of meetings, conferences, training events, award ceremonies and receptions, shall be obtained by the EPA WAM as needed and provided to the Contracting Officer. Work under conference related activities and expenses shall not occur until this approval is obtained and provided by the EPA WAM.

ATTACHMENT 1

QAPP Requirement for Projects Using Existing Data

A project involving existing data gathers and uses existing data for purposes other than those for which they may have been originally collected. These existing data may be obtained from many sources including literature, industry, computerized databases and information systems, and computerized or mathematical models of environmental processes. For projects that use existing data, a QAPP shall be prepared that includes the requirements identified below. If primary data will also be generated as part of the project, then the information below can be incorporated into the associated QAPP to address the existing data. The following requirements should be addressed as applicable.

Section 1. Project Objectives, Organization, and Responsibilities

1.1 The purpose of study shall be clearly stated.
1.2 Project objectives shall be clearly stated.

1.3 The existing data needed to satisfy the project objectives shall be identified. Requirements relating to the type of data, the age of data, geographical representation, temporal representation, and technological representation, as applicable, shall be specified.

1.4 The planned approach for evaluating project objectives, including formulas, units, definitions of terms, and statistical or other types of data analysis. Assumptions and or recommendations based on the data analysis shall also be included if applicable.

1.5 Responsibilities of all project participants shall be identified, meaning that key personnel and their organizations shall be identified, along with the designation of responsibilities for planning, coordination, data gathering, data analysis, report preparation, and quality assurance, as applicable.

Section 2. Sources of Existing Data

2.1 The source(s) of the existing data must be specified.
2.2 The rationale for selecting the source(s) identified shall be discussed.
2.3 The sources of the existing data will be identified in any project deliverable.

Section 3. Quality of Existing Data

3.1 Quality requirements of the existing data must be specified. These requirements must be appropriate for their intended use. Accuracy, precision, representativeness, completeness, and comparability need to be addressed, if applicable. (If appropriate, a related QAPP containing this information can be referenced.)

3.2 The procedures for determining the quality of the existing data shall be described.

3.3 If no quality requirements exist, this shall be stated in the QAPP. If no quality requirements exist or if the quality of the existing data will not be evaluated by EPA, the QAPP shall require that a disclaimer be added to any project deliverable to indicate that the quality of the existing data has not been evaluated by EPA for this specific application. The wording for the disclaimer shall be defined.

Section 4. Data Reporting, Data Reduction, and Data Validation

4.1 Data reduction procedures specific to the project shall be described, including calculations and equations.

4.2 The data validation procedures used to ensure the reporting of accurate project data shall be described.

4.3 The expected product document that will be prepared shall be specified (e.g., journal article, final report, etc.).

ATTACHMENT 2

Office of Water

Information Quality Guidelines:

Pre-Dissemination Review Guidance and Checklists

version 2.2 (January 10, 2003)

BACKGROUND

In order to comply with Section 515 of the Treasury and General Government Appropriations Act for FY 2002 (Public Law 106-554), the Office of Management and Budget developed guidelines that "provide policy and procedural guidance for ensuring and maximizing the quality, objectivity, utility, and integrity of information, including statistical information, disseminated by Federal agencies."

In response to OMB's guidelines (FRL-7157-8, March 2002), EPA developed the Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency (The Guidelines), which contains EPA's policy and procedural guidance for ensuring and maximizing the quality of the information we disseminate. "Quality" refers to objectivity, integrity, and utility.

The Guidelines also:

- Outline administrative mechanisms for EPA pre-dissemination review of information products.
- Enable affected persons to file complaints regarding disseminated information that they believe to be noncompliant with EPA's Guidelines.

Implementation began **October 1, 2002**.

For more information, visit http://www.epa.gov/oei/qualityguidelines/

In order to ensure that information meets The Guidelines, the following guidance and checklists should be used prior to dissemination.

OVERVIEW

- What information is covered under The Guidelines?

- Is your organization in compliance with EPA's existing Quality System and Office of Water's Quality Management Plan?
- What type of information do I have?
- Do additional guidelines apply for externally gathered data?
- Checklists for Pre-Dissemination Review
- What are Requests for Correction and Requests for Reconsideration, and how does OW respond to them?

WHAT INFORMATION IS COVERED UNDER THE GUIDELINES?

These guidelines apply only to information EPA disseminates to the public.

What DO The Guidelines cover?

- EPA prepares the information and distributes it to support or represent EPA's viewpoint, or to formulate or support a regulation, guidance, or other Agency decision or position.
- EPA distributes information prepared or submitted by an outside party in a manner that reasonably suggests that EPA endorses or agrees with it.
- EPA reviews and comments on information distributed by an outside party in a manner that indicates EPA is endorsing it, directs the outside party to disseminate it on EPA's behalf, or otherwise adopts or endorses it.

What DON'T The Guidelines cover?

- Distribution of information for government employees
- EPA response to FOIA, FACA, or similar legislation
- Correspondence directed to individuals or persons
- Information presented solely to Congress
- Ephemeral information (press releases, fact sheets, press conferences)
- Background information (published articles distributed by libraries, or other non-EPA endorsed distributions)
- Information distributed by recipients of EPA grants, contracts, or cooperative agreements unless EPA adopts or endorses the information
- Information in public filings, including information submitted to EPA, either voluntarily or under mandates/requirements
- Distribution of information in judicial cases or administrative adjudication

IS YOUR ORGANIZATION IN COMPLIANCE WITH EPA'S EXISTING QUALITY SYSTEM AND OFFICE OF WATER'S QUALITY MANAGEMENT PLAN?

Many of EPA's current quality assurance practices fulfill much of EPA's Information Quality Guidelines. Examples of these policies are: Quality System, Peer Review, Action Development Process, Integrated Error Correction Process, Information Resources Management Manual, Risk Characterization Policy and Handbook, Program-Specific Policies, and EPA's Commitment to Continuous Improvement. EPA information disseminated to the public must meet EPA's already existing Quality System and other related policies. The Quality System utilizes a graded approach to establish quality criteria that are appropriate for the intended use of the information and the resources available. (The Quality System can be found in EPA Order 5360.1 A2, "Policy and Program Requirements for the Mandatory Agency-wide Quality System" and in the "EPA Quality Manual".)

The Quality System requires Agency organizations to:

- Assign a quality assurance manager
- Develop a Quality Management Plan
- Conduct an annual assessment of the organization's quality system
- Use a systematic planning process to develop acceptance or performance criteria prior to the initiation of all projects that involve environmental information collection and/or use
- Develop Quality Assurance Project Plans for all applicable projects and tasks involving environmental data
- Conduct an assessment of existing data, when used to support Agency decisions or other secondary purposes, to verify accuracy
- Implement all Agency-wide Quality System components in all applicable EPA-funded extramural agreements
- Provide appropriate training for all levels of management and staff

The Office of Water implements EPA's Quality System through its Quality Management Plan, approved by OEI in September 2001. Please refer to this document to ensure that the information you are disseminating complies with Office of Water quality assurance policies.

WHAT TYPE OF INFORMATION DO I HAVE?

Different quality standards apply to influential information, influential scientific risk assessment information, and non-influential information. The definitions of these three types of information are:

Influential: when the Agency can reasonably determine that dissemination of the information will have a clear and substantial impact on important public policies or private sector decisions. These include OMB economically significant actions, peer reviewed documents, top Agency policy documents, and other actions on a case-by-case basis. Influential information must meet a higher standard of quality: "reproducibility".

Reproducibility: providing enough information to allow the public to reproduce our analyses

Influential Scientific Risk Assessment: applies to all dissemination of information regarding human health, environmental, or safety risk assessments, except those conducted under the Safe Drinking Water Act, which will adhere to SDWA principles. Information is required to be accurate, reliable, and unbiased; it should also be comprehensive, informative, and understandable. The quality standard is "objectivity," and uses the following principles:

- Information is accurate, reliable, and unbiased. This involves:
    - Best available science, which utilizes sound and objective scientific practices, and peer review when available
    - Data collection by accepted methods
- Presentation of information is consistent with the purpose of the information, is comprehensive, informative, and understandable. This means specifying:
    - each population addressed by the risk
    - expected risk or central estimate
    - upper-bound and lower-bound estimate of risk
    - significant uncertainties identified
    - peer reviewed studies known to the Administrator

Non-Influential: standard of quality is "transparency."

Transparency: the public can understand how conclusions were obtained on the information

DO ADDITIONAL GUIDELINES APPLY FOR EXTERNALLY GATHERED DATA?

Most external environmental data is within the scope of the Quality System. This includes literature, industry surveys, compilations from computerized databases and information systems, and results from computerized or mathematical models of environmental processes and conditions.

Regarding voluntarily submitted information, EPA will continue to work with States and other governments, the scientific and technical community, and other interested information providers to develop and publish criteria the EPA would use to assess this type of information.

Depending on your information, you need only fill out ONE of the following three checklists. Please forward the checklists to OW's Information Quality Guidelines Officer (currently Leo Gueriguian, 564-0388) for approval and signature. The checklist must then be signed by your Division Director, and a copy sent to your Quality Assurance Officer. Please also note that outside entities may file Requests for Correction (i.e. complaints) to EPA, citing non-compliance with EPA's Information Quality Guidelines.

****Note: OGWDW staff should send their completed checklists directly to their Division Directors. They should work with the OW IQ Guidelines Officer, as their projects and checklists are being developed.**

Office of Water

Information Quality Guidelines Checklist for

Influential Information

Influential Information has or will have a clear and substantial impact on important public policies or private sector decisions. (Includes OMB economically significant actions, peer reviewed documents, top Agency policy documents, and other actions on a case-by-case basis.)

- ❑ The information to be disseminated is covered under The Guidelines.
- ❑ The information is in compliance with EPA's Quality System and other related policies.
- ❑ The information is in compliance with Office of Water's Quality Management Plan.
- ❑ The information is consistent with the OMB definition of "quality," meaning the information has a high level of objectivity, utility, and integrity.
  - ❑ Objectivity: information is presented in an accurate, clear, complete, and unbiased manner, and as a matter of substance, is accurate, reliable, and unbiased.
  - ❑ Integrity: the information cannot be compromised through corruption or falsification because it is secure from unauthorized access or revision.
  - ❑ Utility: the information is useful to the intended users.

- ❑ The information meets "reproducibility" standard.
  The information and its accompanying documentation has a higher degree of transparency regarding the following:
  - ❑ The source of the data used
  - ❑ The various assumptions employed
  - ❑ The analytic methods applied
  - ❑ The statistical procedures employed

_____ _____

Division Director's Signature & Date

IQG Officer for OW Signature & Date

(Officer signature Not needed for OGWDW staff)

**If your information does not comply with any of these items, please attach brief explanation of any omissions. Please forward a copy of this document to your office's Quality Assurance Officer.

version 2.2 (January 10, 2003)

Office of Water

Information Quality Guidelines Checklist for

Influential Risk Assessment Information

Influential Scientific Risk Assessment Information has or will have a clear and substantial impact on important public policies or private sector decisions. (Includes OMB economically significant actions, peer reviewed documents, top Agency policy documents, and other actions on a case-by-case basis.)

- ❑ The information to be disseminated is covered under The Guidelines.
- ❑ The information is in compliance with EPA's Quality System and other related policies.
- ❑ The information is in compliance with Office of Water's Quality Management Plan.
- ❑ The information is consistent with the OMB definition of "quality," meaning the information has a high level of objectivity, utility, and integrity.
  - ❑ Objectivity: information is presented in an accurate, clear, complete, and unbiased manner, and as a matter of substance, is accurate, reliable, and unbiased.
  - ❑ Integrity: the information cannot be compromised through corruption or falsification because it is secure from unauthorized access or revision.
  - ❑ Utility: the information is useful to the intended users.

- ❑ The information meets "objectivity" standard.
  - ❑ The information is accurate, reliable, and unbiased:
    -best available science and supporting studies conducted using sound and objective scientific practices, including peer reviewed studies

    -data were collected by accepted methods or best available methods (if the method's reliability nature of the decision justifies the use of the data)

  - ❑ Presentation of information on human health, safety, or environmental risks, consistent with the purpose of the information, is comprehensive, informative, and understandable. Each of the following must be specified:
    -each population addressed by the risk or each risk assessment endpoint addressed by any estimate of applicable ecological risk

    -expected risk or central estimate for the specific populations affected or the ecological assessment endpoints

    -upper-bound and lower-bound estimate of risk

    -significant uncertainties identified, and studies that would assist in resolving uncertainties

-peer reviewed studies known to the Administrator that support, are directly relevant to, or fail to support any estimate of risk and the methodology used to reconcile inconsistencies in the scientific data

_____ _____

Division Director's Signature & Date

IQG Officer for OW Signature & Date

(Officer signature Not needed for OGWDW staff)

**If your information does not comply with any of these items, please attach brief explanation of any omissions. Please forward a copy of this document to your office's Quality Assurance Officer.

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 3-77

☐ Other ☒ Amendment Number: 000001

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-14-001	11/01/2013 To 10/31/2017 Base Option Period Number 3	Secondary Contact Water Qualit

Contractor	Specify Section and paragraph of Contract SOW
ICF INCORPORATED, L.L.C.	III.D, III.E.1, III.G

Purpose:
- ☐ Work Assignment
- ☒ Work Assignment Amendment
- ☐ Work Plan Approval
- ☐ Work Assignment Close-Out
- ☐ Incremental Funding

Period of Performance: From 11/01/2016 To 10/31/2017

Comments:
This amendment adds Task 4 to the work assignment.

☐ Superfund — Accounting and Appropriations Data — ☒ Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (*Max 2*) ☐

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
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Authorized Work Assignment Ceiling

	Contract Period:	Cost/Fee:	LOE:
	11/01/2013 To 10/31/2017		
This Action:			
Total:			

Work Plan / Cost Estimate Approvals

Contractor WP Dated:	Cost/Fee	LOE:
Cumulative Approved:	Cost/Fee	LOE:

Work Assignment Manager Name: Gary Russo (Signature) (Date)	Branch/Mail Code: Phone Number: 202-566-1335 FAX Number:
Project Officer Name: Melissa Revely-Wilson (Signature) (Date)	Branch/Mail Code: Phone Number: 919-541-0207 FAX Number:
Other Agency Official Name: (Signature) (Date)	Branch/Mail Code: Phone Number: FAX Number:
Contracting Official Name: William Yates (Signature) (Date)	Branch/Mail Code: Phone Number: 513-487-2055 FAX Number:

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 3-79

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-14-001	11/01/2013 To 10/31/2017 Base Option Period Number 3	Toxicity Pathways Workgroup

Contractor	Specify Section and paragraph of Contract SOW
ICF INCORPORATED, L.L.C.	A. 1, B. D. E. G

Purpose:
- ☒ Work Assignment
- ☐ Work Assignment Amendment
- ☐ Work Plan Approval
- ☐ Work Assignment Close-Out
- ☐ Incremental Funding

Period of Performance: From 11/01/2016 To 10/31/2017

Comments:

☐ Superfund — Accounting and Appropriations Data — ☒ Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (*Max 2*) ☐

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
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4										
5										

Authorized Work Assignment Ceiling

Contract Period: 11/01/2013 To 10/31/2017 — Cost/Fee: — LOE:

This Action:

Total:

Work Plan / Cost Estimate Approvals

Contractor WP Dated: — Cost/Fee — LOE:

Cumulative Approved: — Cost/Fee — LOE:

Work Assignment Manager Name: Catherine Gibbons (Signature) (Date)	Branch/Mail Code:	
	Phone Number: 703-603-0704	
	FAX Number:	
Project Officer Name: Melissa Revely-Wilson (Signature) (Date)	Branch/Mail Code:	
	Phone Number: 919-541-0207	
	FAX Number:	
Other Agency Official Name (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	
	FAX Number:	
Contracting Official Name: William Yates (Signature) (Date)	Branch/Mail Code:	
	Phone Number: 513-487-2055	
	FAX Number:	

PERFORMANCE WORK STATEMENT
CONTRACT NO. EP-C-14-001
WA 3-79

TITLE: Support for the Analysis, Evaluation, and Synthesis of Mechanistic Data for the Toxicity Pathways Workgroup (TPWG)

Specify Section & Paragraph SOW:

A. Assessment Issues and Documents
1. Human Health Assessment Documents
B. Risk Assessment Data Bases and Computer Tools exposure assessment
D. Analysis, Document and Issue Paper Preparation
E. Risk Assessment Support
G. Literature Search

PERIOD OF PERFORMANCE: *11/1/16 to 10/31/17*

I. PURPOSE

The purpose of this Work Assignment is to provide services to the U.S. Environmental Protection Agency's (hereinafter EPA or Agency) National Center for Environmental Assessment (NCEA), Office of Research and Development (ORD), related to the analysis, evaluation, and synthesis of mechanistic data to support carcinogenic and noncancer mode of action evaluations in IRIS Toxicological Assessments. Specifically, support may include focused literature searches and support for the HERO database, continued development of the cellDRAGON database and user interface, and optional support for further evaluation and synthesis of mechanistic evidence, primarily for the preparation of toxicological reviews by NCEA's IRIS Program.

II. BACKGROUND

EPA's IRIS Program is an assessment program that evaluates qualitative and quantitative information on human health effects that may result from exposure to chemicals found in the environment. Through the IRIS Program, EPA provides science-based human health assessments to support the Agency's activities. The IRIS database contains hazard characterization and toxicity values for the first two steps of the risk assessment process—hazard identification and dose-response assessment. By combining IRIS toxicity values with information on chemical exposure, government and other entities can characterize health risks of chemicals.

EPA's process for developing IRIS assessments consists of: (1) draft development, which includes a public meeting focused on identifying the available scientific information; a comprehensive search of the scientific literature; release of preliminary materials (literature search and associated search strategies, evidence tables, and exposure-response figures); and a public meeting to discuss the early materials; (2) EPA-wide internal review; (3) science consultation on the draft assessment with other Federal agencies and the Executive Office of the President; (4) public review and comment, including a public meeting to discuss the draft assessment and draft peer review charge, and independent expert peer review; (5) revision of the assessment to address peer review and public comments; (6) a second EPA-wide internal review and interagency discussion with other Federal agencies and the Executive Office of the President; and (7) posting of the final assessment to the IRIS website (www.epa.gov/iris/).

The Toxicity Pathways Workgroup (TPWG) is tasked with reviewing and evaluating mechanistic studies for all IRIS toxicological reviews, for both cancer and noncancer health outcomes, and for synthesizing this evidence and evaluating hypothesized modes of action for identified potential human health hazards.

Under a previous contract, software utilities (DRAGON and BMDS-WIZARD) were developed for IRIS. These tools are based on Microsoft Access, MS/Excel, some VBA code, and BMDS software. The purpose of these tools is to expedite the entry and QA of information and data from toxicological studies, to expedite the production of tables for IRIS chemical assessments, and to expedite the conduct of dose-response analysis and related calculations and the review and reporting of results. These tools have greatly increased throughout and decreased effort for assembling and reporting information for IRIS assessments. CellDRAGON is being adapted from DRAGON to capture study details on methods and results from mechanistic studies and facilitate analyses of these data.

This PWS addresses the following step of the IRIS process for assessment development: Step 1—development of the draft Toxicological Review (http://www.epa.gov/iris/process.htm). In this process, the Contractor shall follow applicable EPA guidance (see http://www.epa.gov/iris/backgrd.html).

III. STATEMENT OF WORK

Task 1: Establish Communication

Within 3 days of start date of this WA, the Contractor shall schedule a conference call (not to exceed 1 hour) with the WAM and appropriate contractor staff to clarify outstanding questions and confirm the schedule and specific tasks.

Task 2: Work Plan, Staffing Plan, and Quality Assurance Project Plan (QAPP)

The Contractor shall prepare a Technical Work Plan describing how the work outlined in this Performance Work Statement will be performed, including deliverables, a schedule, budget, and level of effort. The Contractor shall also prepare a Staffing Plan, which shall be submitted as part of the Work Plan, which shows assigned personnel by task and the qualifications of the proposed personnel. The Contractor shall provide expertise in the areas of toxicology, pharmacology, physiology, chemistry, statistics, and library science. A working knowledge of risk assessment methodology and EPA risk assessment guidelines is required.

The Contractor shall develop a QAPP for approval by the WAM and Quality Assurance Manager. The Contractor must address in the QAPP how they are going to consider the use of secondary data to carry out this task. Secondary data are defined as environmental or health data that were developed for a different purpose. This includes data used from citations found in the literature. See these documents: "*EPA Manual C/0 2105-P-01-0: EPA Quality Manual for Environmental Programs* (QAPP)"; "*EPA Requirements for Quality Assurance Project Plans (QA/R-5)*"; "Appendix A. *Guidance on Quality Assurance Project Plans for Secondary Research Data*"; "*EPA 100/B-03/001: A Summary of General Assessment Factors for Evaluating the Quality of Scientific and Technical Information* (2003)," and the addendum, "*Guidance for Evaluating and Documenting the Quality of Existing Scientific and Technical Information* (2012)."

The QAPP shall be submitted simultaneously with the Work Plan for approval.

Task 3: Maintenance of the HERO Database for Mechanistic Literature

The Contractor shall perform the following to ensure the HERO database is up to date for mechanistic studies identified in literature searches for chemicals being reviewed and evaluated by the TPWG:

- Following initial literature search and tagging, ensure that the full-text copy (i.e. PDFs) of all literature tagged as "mechanistic" are available through HERO. This may be performed initially by working with HERO staff to implement a batch full-text download for the entire database of tagged mechanistic studies.

- Ensure that literature listed in HERO for a particular search are appropriately tagged to the correct chemical project and bin.

Ensure that PDFs of references not previously identified in original literature search (i.e., retrieved during draft development, literature search update and/or referenced in the IRIS document) are uploaded to HERO and tagged appropriately.

Task 4. DRAGON (Dose Response Analytical Generator and Organizational Network)

This Task covers additions to and modifications of cellDRAGON only, except where it may be necessary to integrate this module into a single database system. EPA expects to request additions of new data fields and simple calculations in cellDRAGON, to support reporting needs for evidence tables. For the purpose of costing this PWS, the contractor should assume that a dozen such changes may be requested by EPA. Changes or additions to data fields for developmental studies can be expected. Export and import capabilities (e.g. for data exchange with Meta-data Viewer, Graphpad, and MS Excel, as well as importing into document formatting software, currently MS Word) may be requested. Forms, or export capabilities, or reporting formats compatible with HERO may be requested.

Additions of data fields and capabilities may include specialized fields for relevant health effects, study designs, and assays measuring endpoints that fall into designated mechanistic categories (e.g., micronucleus assay, which measures chromosomal aberrations and aneuploidy, under the "genotoxic" category, etc.). Modifications to cellDRAGON are expected to be iterative, with periodic evaluation performed using 'test' or 'practice' sets of data/studies. The contractor will verify correct operation of cellDRAGON during development and after completion of a beta version, and will report periodically to the WAM on results of testing and on measures to correct any problems found by testing or in use. This work assignment will continue and extend development of cellDRAGON but shall not duplicate work already done for the federal government. [For example, modifications to cellDRAGON made under another work assignment would not be repeated under this work assignment.]

Deliverables and due dates:
Requests for new and revised fields and forms will be specified in written technical direction
Drafts of cellDRAGON for review - arranged by consultation with WAM
Reports on testing with 'practice data' – approx. every 4 weeks or as directed by WAM during development
Word report/table templates – to be requested in written technical directions

Task 5. User Manuals and Tutorials

User manuals will be developed for cellDRAGON (these will also cover use of the imbedded dosimetry tool). Scope: the manuals will provide users with instructions sufficient for end-use, but are not expected to explain the workings of Access or Excel or the details of the associated VBA code. Manuals will be provided with databases that may be used in the manuals as examples and can be used by users as templates. Necessary information will be provided separately on any modifications (including VBA code) and configuration steps needed to use these databases on a proxy server. Manuals will be revised within one month of any significant changes to cellDRAGON.

Tutorials will be provided (dates to be determined in consultation with EPA). These may take the form of demonstration/lectures, either on-site at EPA locations or as webinars. Provision will be made for user questions and answers. For the purpose of costing this PWS, the contractor should assume that EPA would request eight demonstration/lectures, four at each of two EPA locations. Some might be conducted via webinar, but others might be in-person at different EPA locations.

The manuals and tutorials may have already been drafted/planned under another work assignment; this work assignment shall not duplicate work already done for the federal government.

Deliverables and due dates:
Manuals: draft within 15 working days of consultation with WAM regarding this task; revised drafts within 10 working days after EPA returns comments

Tutorials: dates to be arranged in consultation with EPA

Task 6. User Group Meetings

Meetings will be arranged as telephone conferences and/or web conferences. The contractor shall coordinate and organize meetings, distribute agendas, and report minutes and action items.

Meeting frequency will be determined by consultation with EPA; expected frequency is monthly to bi-monthly, but ad-hoc meetings may be called (as needed) to discuss new modules and new or changed features. Details of attendees and subject matter will be arranged in consultation with EPA. The principal purposes are (a) to gather input from users in the TPWG regarding cellDRAGON features and usability (existing or planned) and (b) to share information about and reconcile needs of different users both within EPA (including HERO users and staff) and in other federal agencies.

This work assignment will continue and extend development of cellDRAGON but shall not duplicate work already done for the federal government.

Deadlines: meeting dates and times to be determined in consultation with EPA and other users

OPTIONAL TASKS

The following tasks are optional. If EPA determines the services under these tasks are required, the EPA WAM will initiate by issuing written technical direction. These optional tasks should be addressed in the technical proposal and included in the cost proposal of the work plan.

Optional Task 7: Preparation and Quality Assurance of Mechanistic Evidence Tables

Optional Task 7a: Preparation of Evidence Tables for Mechanistic Studies

The Contractor may be directed to provide support to EPA in preparing evidence tables and simple graphics that summarize genetic toxicity and/or other mechanistic studies. There are two phases of tables and/or graphics that may be generated:

1) Preliminary categorization of mechanistic studies: In the early stages of the assessment, following identification of mechanistic literature, basic mechanistic study information will be extracted into either cellDRAGON or into MS Access or Excel spreadsheets for assessments prior to optimization of cellDRAGON. Basic graphics representing the overall findings will accompany these tables. Further details of examples of tables containing the information requested will be provided to the Contractor by the WAM.

2) Selected mechanistic evidence tables: During the synthesis phase of draft development, mechanistic evidence tables will be developed that emphasize crucial aspects of the data. These may include tables generated from data entered into cellDRAGON. If these studies are not already in cellDRAGON, the WAM will provide the Contractor with an endnote file or Excel spreadsheet containing these studies and any existing work on selecting and organizing the studies. Examples of tables containing the information requested will also be provided to the Contractor by the WAM.

Optional Task 7b: Update and Quality Assurance of Mechanistic Evidence Tables

The Contractor may be directed to provide support to the TPWG in performing updates and quality assurance checks of tables that summarize mechanistic studies and data. Updates of these tables shall be performed to add new studies identified through literature search updates performed during development of the draft assessment or during review steps. Quality assurance checks shall include the following: comparison of table entries to

information from the original publication, checking conversions as appropriate (e.g., ppm to mg/m^3), confirming effect levels, and inserting and verifying HERO links. For each health effect category, separate evidence tables will be developed (if data are available), and all routes of exposure will be considered in the absence of more specific technical direction. The quality assurance check should be performed by a scientist that was not involved in the initial development of the table being reviewed. These tables will be provided to the Contractor by the WAM.

Optional Task 8: Update Literature Search Specific to Mechanistic Studies Database

If the TPWG determines that a new literature search must be conducted that is more specific to a mechanism of carcinogenicity identified in the original literature search, the Contractor shall perform this literature search and/or update at the direction of the WAM. The literature search strategy shall be consistent with the strategy for other literature searches conducted by ICF and with the latest draft of the Handbook for IRIS Assessment Development. The Contractor shall add new references to HERO, tag references consistent with existing tags in HERO, and document the updated literature search strategy and findings.

If questions arise during the literature search and screening task (e.g., difficulties in narrowing down the number of "hits" from the search, questions about the relevance of certain types of papers or topics, retrieval of difficult to obtain documents or foreign language papers), the Contractor shall contact the WAM for further guidance.

Optional Task 9: Synthesis of Mechanistic Evidence for Mode of Action Evaluation

The TPWG may require support from the Contractor for synthesizing the mechanistic information that has been organized into tables. This task may vary in complexity depending on the specific request for a chemical assessment. For example, the following syntheses may be requested:

- A concise, higher-level overview of mechanistic events theorized to be operant and/or hypothesized modes of action (MOAs) based on the data available (i.e., a short, 2-4 page summary), including some indication of what highly informative data may be missing (a "summary" as described in the IRIS Handbook, Chapter 6.3.2)
- An evaluation of mechanistic evidence, assembling it into groups or nodes corresponding to hypothesized mechanistic events or "key events," with suggestions of more specific MOAs and/or adverse outcome pathways or networks (AOPs) that will be further analyzed by the TPWG (IRIS Handbook Chapter 9.3.2)
- A highly detailed evaluation of mechanistic evidence, including construction and analysis of hypothesized MOAs and/or AOPs, and the weight of evidentiary support for each (IRIS Handbook Chapter 9.3.3)
- General consultation, including comments, suggestions, or constructive feedback upon review of TPWG-generated materials falling into the above categories

The Contractor shall contact the WAM for specific guidance or instructions.

Optional Task 10: Identify, Recruit, and Manage Scientists with Expertise in the Mechanisms of Carcinogenesis

The Contractor may be directed to identify, recruit, and manage experts in the mechanisms and pathways of chemical carcinogenesis ("experts") to develop or review sections of IRIS Toxicological Reviews and/or related materials. The Contractor shall be responsible for ensuring timely communication is passed between the EPA work assignment manager (WAM) and the experts so that technical clarification can be offered and interaction between EPA and the experts can occur as needed. The Contractor shall also ensure that the deliverables are provided to the EPA WAM in a timely manner.

EPA will provide direction and examples and/or templates for the specific work requested from the expert, which could include: consultation and participation in topical TPWG discussions; study methods evaluation; evidence identification, evaluation, and synthesis of mechanistic evidence and hypothesized MOAs and/or AOPs; or guidance

on the development of evidence and summary tables, or MOA/AOPs developed by the TPWG. The chemical assessments and related documents that will require assistance under this PWS will be clarified through technical direction.

The EPA assumes primary authorship in the writing process for all materials and contributing experts are listed in the final documents as appropriate. EPA will approve each of the experts performing work within two days of notification of a potential candidate.

1) Identify and Recruit Cancer Experts: The Contractor shall identify and contact experts with a knowledge base that is aligned with the descriptions in each written technical directive (TD). Each TD will specify the minimum/desired qualifications of the experts for that chemical assessment. The expertise needed will be specific within the broad field of carcinogenesis. Potential experts shall be asked to submit a bio-sketch to ensure they meet the minimum/desired qualifications, and EPA will notify the contractor of its concurrence with the selection.

2) Manage Cancer Experts: The Contractor shall manage the recruited experts and ensure timely communication occurs between EPA and the experts. This shall involve setting up conference calls with the experts and EPA staff. In addition, the Contractor shall ensure that the written sections, comments and draft reviews are progressing on schedule and are delivered by the deadlines noted in this WA.

Deliverable Schedule: The schedule and specific expertise requested will be clarified within a TD.

IV. ANTICIPATED DELIVERABLES

All products by the Contractor must be of high quality, written in a clear concise style, with a logical organization and presentation.

V. DELIVERABLES AND SCHEDULE

Task	Deliverable Due Date
Task 1. Initial Conference Call	3 days after award of Work Assignment
Task 2. Staffing Plan and QAPP	15 days after award
Task 3: Maintenance of HERO Database	No more than 30 days after discussion with WAM.
Task 4: cellDRAGON	Drafts of cellDRAGON for review: arranged by consultation with WAM
	Oral reports on testing with practice data or in use for EPA projects – approx. every 4 weeks during development
	Beta versions of cellDRAGON after adding new modules - arranged by consultation with WAM
	Revisions in response to EPA comments - 14 work days after receiving technical direction
Task 5: User Manuals and Tutorials	Manuals: draft within 15 working days of consultation with WAM regarding this task; revised drafts within 10 working days after EPA returns comments
	Tutorials: dates to be arranged in consultation with EPA
Task 6: User Group Meetings	To be determined in consultation with EPA and other users
Optional Task 7a: Preparation of Evidence Tables for Mechanistic Studies	No more than 45 days after discussion with WAM

Task	Deliverable Due Date
Optional Task 7b: Update and Quality Assurance of Mechanistic Evidence Tables	No more than 20 days after discussion with WAM
Optional Task 8: Updates to Literature Search Specific to Mechanistic Studies Database	For each update, no more than 30 days after initiation of literature search
Optional Task 9: Synthesis of Mechanistic Evidence for Carcinogenesis	45 days after discussion with the WAM
Optional Task 10: Identify, Recruit, and Manage Scientists with Expertise in the Mechanisms of Carcinogenesis	To be determined based on scope of work outlined in TD

Note: All days are calendar days.

VI. MANAGEMENT CONTROLS

1. All deliverables shall be reviewed for conformance to the requirements of this work assignment before being approved as final.

2. The contractor shall comply with other applicable requirements for final work assignment reports stipulated in contract.

VII. NOTICE REGARDING GUIDANCE PROVIDED UNDER THIS PROJECT

Guidance is strictly limited to technical and analytical support. The contractor shall not engage in activities of an inherent governmental nature such as the following:

(1) Formulation of Agency policy
(2) Selection of Agency priorities
(3) Development of Agency regulations

Should the contractor receive any instruction from an EPA staff person that the contractor ascertains to fall into any of these categories or goes beyond the scope of the contract or work assignment, the contractor shall immediately contact the PO, WAM, or CO.

VIII. SPECIAL CONDITIONS AND ASSUMPTIONS

The contractor shall hold a conference call with the EPA WAM at the initiation of the work assignment, and shall provide a bi-weekly update to the WAM by telephone for the duration of the work assignment, in addition to the standard reporting requirements of the contract.

IX. EPA CONTACT INFORMATION

Copies of all correspondence pertaining to the performance of this work assignment shall be sent to the PO.

Work Assignment Manager (WAM):

Catherine F. Gibbons, PhD
Telephone: 703-603-0704
Fax: 703-347-8689
e-mail: gibbons.catherine@epa.gov

Mailing Address:

U.S. Environmental Protection Agency
Office of Research and Development
National Center for Environmental Assessment (MC 8601P)
1200 Pennsylvania Ave. NW
Washington, DC 20460

Overnight Delivery location:
U.S. Environmental Protection Agency
Office of Research and Development
National Center for Environmental Assessment
One Potomac Yard (S-11226)
2777 S. Crystal Drive
Arlington, VA 22202

Alternate WAM:

Jason Fritz
Telephone: 703-347-0332
Fax: 703-347-8689
e-mail: fritz.jason@epa.gov

Mailing Address:
U.S. Environmental Protection Agency
Office of Research and Development
National Center for Environmental Assessment (MC 8601P)
1200 Pennsylvania Ave. NW
Washington, DC 20460

Overnight Delivery location:
U.S. Environmental Protection Agency
Office of Research and Development
National Center for Environmental Assessment
One Potomac Yard (S-11217)
2777 S. Crystal Drive
Arlington, VA 22202

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 3-81

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-14-001	11/01/2013 To 10/31/2017 Base Option Period Number 3	Mapping Vulnerability to Clima

Contractor	Specify Section and paragraph of Contract SOW
ICF INCORPORATED, L.L.C.	A, A2d,A3, B,B.1,C.,c.4,d.,e.,F.

Purpose:
- [X] Work Assignment
- [ ] Work Assignment Amendment
- [ ] Work Plan Approval
- [ ] Work Assignment Close-Out
- [ ] Incremental Funding

Period of Performance: From 11/01/2016 To 10/31/2017

Comments:

☐ Superfund — Accounting and Appropriations Data — [X] Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (*Max 2*) ☐

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

Contract Period: 11/01/2013 To 10/31/2017 — Cost/Fee: — LOE:

This Action:

Total:

Work Plan / Cost Estimate Approvals

Contractor WP Dated: — Cost/Fee — LOE:

Cumulative Approved: — Cost/Fee — LOE:

Work Assignment Manager Name: Janet Gamble (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	703-347-8617
	FAX Number:	
Project Officer Name: Melissa Revely-Wilson (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	919-541-0207
	FAX Number:	
Other Agency Official Name (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	
	FAX Number:	
Contracting Official Name: William Yates (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	513-487-2055
	FAX Number:	

PERFORMANCE WORK STATEMENT

Contract # EP-C-14-001

WA Option # 3-81

Title: Mapping the Vulnerability of Human Health to Climate Change in the United States

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PERIOD of PERFORMANCE: 11/01/2016 – 10/31/2017

Specify Section & Paragraph SOW: A., A.2.d., A.3., B. B.1.g., C.1., C.4., D., E & F

NOTE: This work assignment is a follow-on to work performed in the Year 2 Option Period under Work Assignment # 2-81. The work continues for Task 5 during this Year 3 Option Period under Work Assignment # 3-81. This PWS outlines the Task 5 Deliverables. Tasks 1-4 from Option Year 2 have been completed. No new funds are included in this WA # 3-81, rather, those funds remaining from Option Year 2 are to be rolled forward.

I. PURPOSE

The purpose of this work assignment is to provide services to the U.S. Environmental Protection Agency's National Center for Environmental Assessment (NCEA), Global Change Research Program (GCRP) for developing methodologies for mapping the impacts of climate change on the vulnerability of human health and well-being in the U.S. and considering the adaptation strategies that may be supported by vulnerability maps.

II. OBJECTIVES

This project addresses a seemingly modest but complex question: "How straightforward is it to map the vulnerability of human health, across a number of factors or dimensions, for the entire United States in a meaningful and self-consistent way (see U.S. EPA, 2011)?"

The overarching objective for this project is to provide public health, public safety, urban planning, emergency response officials and other stakeholders with geospatial methods and maps for identifying and understanding key vulnerabilities, communicating risks to vulnerable populations, and planning and prioritizing location-specific adaptation responses. Other objectives include:

- Identifying and summarizing an array of indicators that may be used to derive vulnerability maps;
- Engaging subject matter experts (SMEs) to identify approaches currently used to assess vulnerability, map health impacts, and prepare location-specific adaptation strategies.

Mapping vulnerability is conceptually and technically demanding. We are exploring key challenges associated with vulnerability mapping, especially the lack of consensus regarding mapping methods and the result that some analytic approaches have, at times, been based on convenience or familiarity as opposed to efficacy, generalizability, and comparability. This project will compile guidance for vulnerability mapping, including:

- Research to identify and evaluate mapping methodologies for understanding vulnerabilities (including, local, regional, and national map overlays) to climate-related stressors and to the interaction with other demographic, socioeconomic and environmental stressors.
- A survey of applications that support information integration for standardizing and mapping spatial data drawn from large health, demographic, land use / land cover, climate data sets, and other important data sources.

- Making the connection between vulnerability mapping and approaches for adaptation, especially addressing opportunities for improved risk communication and targeted emergency response and,
- Determining how uncertainty, model complexity, generalizability, and comparability can be addressed across a range of mapping methodologies.

This project focuses on a "hands on" approach. The intended audience for the vulnerability maps is expected to include professionals engaged in community-based research and adaptation planning, community and urban planners and geographers; land use and transportation planners; public health and safety officials; emergency preparedness and response professionals; environmental health scientists; community organizers; and, other stakeholders, both in and out of government and academia and other non-governmental organizations (NGOs) across national, regional, state and local scales.

III. BACKGROUND

The EPA Global Change Research Program focuses on the impacts of climate change on human health, air quality, water quality, and aquatic ecosystems. Climate impacts include, but are not limited to, increases in warmer and more frequent hot days and nights; increases in excess heat events; increases in heavy precipitation and flooding; increases in areas affected by drought and wildfires; increases in the intensity of tropical storms and storm surge; and sea level rise (Melillo 2014). In addition to climate factors contributing to health outcomes, human health is influenced by non-climate factors, such as economic status, the adoption of new technologies, the condition of the built environment and infrastructure, available human and social capital, political and social institutions, land-use / land-cover changes, demographic trends, accessibility and affordability of health care, and specific health impacts.

Within the United States, climate change is expected to contribute to a range of health impacts for vulnerable populations. The extent and nature of climate change impacts on human health vary by location, by the relative vulnerability of specific population groups, by the extent and duration of exposure to climate change (including, for example, heat and extreme weather events), and by society's ability to adapt to or cope with climate change.

We propose to identify and define methodologies for developing maps and mapping tools that allow for an assessment of the health impacts of climate change on vulnerable populations. Using GIS tools, analysts can develop maps that demonstrate the impacts of climate change, such as extreme weather events, tropical storms, river and coastal flooding, droughts and wildfires, extreme heat, and sea level rise. An index of adaptive capacity (which is a function of factors such as income, life expectancy, educational attainment, literacy, adoption of new technologies, and condition of existing infrastructure) can also be mapped.

Some satellite remote-sensing instruments now have a degree of spatial resolution that allows for finer-scale analyses. High-resolution remote sensing technologies enable the mapping of land cover and land use, and thermal profiles and can be integrated, through the use of Geographic Information Systems (GIS), with indicators of social vulnerability such as demographic trends, income, measures of economic productivity, condition of housing stocks, extent of air-conditioning usage, access to and the condition of transportation infrastructure, and accessible and affordable health care services. The refinement of mapping techniques may mean that emergency personnel will improve their response to extreme events and allow better resource allocation and tailoring of communications and adaptation strategies for vulnerable populations in at-risk locations.

Prior to the initiation of this WA, EPA staff will review the draft findings from a literature review conducted as part of the US Global Change Research Program's Climate Health Assessment to identify projects, reports, or indicators, focused on mapping vulnerability of human health to climate change. EPA staff is developing a survey of vulnerability mapping projects that introduces a conceptual framework that defines vulnerability mapping and highlights mapping studies for which data sources may be available. Existing or planned projects

that employ mapping methodologies will incorporate a variety of materials, including: peer reviewed journals, grey literature, conference proceedings and reports, NGO and Government reports, and information describing existing vulnerability mapping projects, and health indicators.

The USGCRP Climate Health Assessment includes a chapter on Populations of Concern (Chapter 9) that addresses health impacts and vulnerability mapping across population groups. In addition, the EPA Staff has begun to identify and classify vulnerability mapping projects with information that includes: investigator contact information; location and scale of project; vulnerability indicators used; data sources and their availability, utility and reliability; methodologies used for developing map overlays; types of spatial-analytic techniques employed; approaches for disseminating maps and creating visualization of risks; and, lessons learned from each mapping project.

IV. INTENDED AUDIENCE and UTILIZATION of PROJECT PRODUCTS.

The intended audience/user for this project's outputs is the Office of Air and Radiation (OAR) Climate Change Division (CCD) and partners from the Sustainable and Healthy Communities (SHC) National Program at EPA/ORD and outside public health researchers, practitioners, and policy planners. Representatives from these audiences may be invited to participate in the one-on-one interviews and the experts' technical working group meeting. Other EPA Program and Regional Offices are expected to utilize the report and its mapping methodologies and analyses to understand the vulnerability of populations to the health impacts associated with climate change based on geographic location. We will seek input from federal agencies represented in the membership of the USGCRP's Climate Change and Human Health Working Group (CCHHG). We anticipate opportunities to present this project to and seek engagement from federal partners in the CCHHG. Subject matter experts will be identified by federal, state, and local mapping experts from within and outside of government. The non-governmental experts are limited to nine or fewer. The total of federal, academic and NGO SMEs is eleven.

V. REQUIRED CONTRACTOR QUALIFICATIONS.

The Contractor shall provide multidisciplinary professional expertise in assessing the impacts of climate change on human health and human well-being, especially related to developing best practices for applying geo-spatial mapping techniques to assess the vulnerability of specific locations/populations to the human health impacts of climate change. Expertise related to vulnerability mapping and public health adaptation strategies that address climate change impacts is required. In addition, experience is required in preparing technical reports consistent with the standards of the peer-reviewed literature. The proposed scientific and technical authors shall be recognized in their fields, and they shall have the general knowledge, as well as the specific knowledge, expertise, or experience, specified in the work assignment. The selected authors must have experience that includes authoring journal articles or other technical documents that specifically relate to this topic.

VI. BACKGROUND related to Option Year 2 WA # 2-81, Tasks 1-4

NOTE: This work assignment # 3-81 is a follow-on to work performed in the Year 2 Option Period under Work Assignment # 2-81. The work continues for Task 5 during this Year 3 Option Period under Work Assignment # 3-81. Tasks 1-4 from Option Year 2 are complete (see below).

Task 1: Communication, Work Plan, Cost Estimate, and Quality Assurance Statement (**Completed**)
Task 2: Routine and ongoing communication activities. (**Current**)
Task 3: One-on-one interviews with subject matter experts. (**Completed** April-July 2016)
Task 4: SME Workshop and report out (**Completed** August-September 2016)

Summary of completed Tasks 1-4: An initial Synthesis Report entitled "Mapping the Vulnerability of Human Health to Climate Change in the United States" was prepared by the Contractor using the transcripts from the one-on-one interviews with the eleven Subject Matter Experts (SMEs) conducted in April, 2016. The WAM reviewed and edited this initial report and forwarded it to the SMEs for their review prior to the August 12, 2016 SME workshop in Washington, DC. At the workshop and in the days that followed, additional input was received from the SMEs and transcripts of the workshop were prepared by the Contractor and provided to the WAM. Using the transcripts from the workshop, the WAM revised the Synthesis Report and prepared an Internal Review Draft (IRD) for review by 2 EPA scientists. The internal reviewers include one National Center for Environmental Assessment (NCEA) scientist and one EPA scientist in the Office of Research and Development. The WAM prepares a response to these internal reviews and edits the report to address their comments. The WAM prepares the External Review Draft (ERD) based on the IRD review process.

VII. UPDATED STATEMENT of WORK for Option Year 3, Task 5

Option Year 3, Task 5: External Review and Preparation of a final EPA Report.

Deliverable 5.1: Following the completion of the internal review, the Contractor shall recruit 3-4 external reviewers to provide comments and edits on the External Review Draft report. The Contractor shall identify external reviewers who are experts, for example, on the human health impacts of climate change; the use of vulnerability mapping to characterize spatial distribution of health impact data; the derivation of social vulnerability indicators associated with assessing the impacts of climate change; state or local public health and safety officials and community planners who utilize maps to implement adaptations to climate change; emergency preparedness and response professionals; and other stakeholders both in and out of government, academia or other NGOs who may use maps to characterize at-risk populations and implement adaptations.

Deliverable 5.2: The Contractor and the WAM shall develop a list of questions as guidance for the external reviewers. External reviewers will be requested to complete their reviews within 3-4 weeks of receiving the ERD.

Deliverable 5.3: *The external reviewers' responses shall be compiled by the Contractor in an Excel* spreadsheet that is formatted *according to the WAM's* directions.

Deliverable 5.4: Using the compiled external reviewer comments, the WAM will respond to edits and prepare a final EPA report. The Contractor will organize and prepare this version of the report according to guidance provided by the WAM regarding templates for preparing and formatting EPA Reports.

VIII. DELIVERABLE TIMELINE for WA # 3-81, Task 5

Task	Description	Deliverable Timeline
TASK 5	**A draft Synthesis Report shall be prepared for external review and final formatting as an EPA Report**	
5.1	Contractor recruits 3-4 external reviewers	FY 2017 Q 1
5.2	Contractor and WAM develop questions to guide the external review	FY 2017 Q 1
5.3	Contractor compiles external reviewers' responses in a spreadsheet as directed by the WAM	FY 2017 Q 2
5.4	WAM prepares final EPA report and Contractor prepares formatted report according to guidance from the WAM	FY 2017 Q 3

IX. MANAGEMENT CONTROLS

1. All deliverables shall be reviewed for conformance to the requirements of this work assignment before being approved as final.

2. The contractor shall comply with other applicable requirements for final work assignment reports stipulated in contract.

X. NOTICE REGARDING GUIDANCE PROVIDED UNDER THIS PROJECT

Guidance is strictly limited to technical and analytical support. The contractor shall not engage in activities of an inherent governmental nature such as the following:

(1) Formulation of Agency policy
(2) Selection of Agency priorities
(3) Development of Agency regulations

Should the contractor receive any instruction from an EPA staff person that the contractor ascertains to fall into any of these categories or goes beyond the scope of the contract or work assignment, the contractor shall immediately contact the PO, WAM or CO.

XI. SPECIAL CONDITIONS AND ASSUMPTIONS

The contractor shall hold a conference call with the EPA WAM at the initiation of the work assignment, and shall provide a bi-weekly update to the WAM by telephone for the duration of the work assignment, in addition to the standard reporting requirements of the contract.

XII. EPA CONTACT INFORMATION

Copies of all correspondence pertaining to the performance of this work assignment shall be sent to the WAM.

Work Assignment Manager (WAM):

Janet L Gamble, PhD
Telephone: 703-347-8617
FAX: 703-347-8694
Email: gamble.janet@epa.gov
Postal Address: 1200 Pennsylvania Ave, NW; Mailcode 8601P; Washington, DC 20460
Physical Address: USEPA; One Potomac Yard (South) S11926; 2777 S Crystal Dr, Arlington, VA 22202

Alternate Work Assignment Manager (WAM):

Anne Grambsch
Telephone: 703-347-8521
FAX: 703-347-8694
Email: grambsch.anne@epa.gov
Postal Address: 1200 Pennsylvania Ave, NW; Mailcode 8601P; Washington, DC 20460
Physical Address: USEPA, One Potomac Yard (South) S11955, 2777 S Crystal Dr, Arlington, VA 22202

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 3-83

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-14-001	11/01/2013 To 10/31/2017	PBPK Modeling
	Base Option Period Number 3	

Contractor: ICF INCORPORATED, L.L.C.

Specify Section and paragraph of Contract SOW:

Purpose:
- [X] Work Assignment
- [ ] Work Assignment Amendment
- [ ] Work Plan Approval
- [ ] Work Assignment Close-Out
- [ ] Incremental Funding

Period of Performance: From 11/01/2016 To 10/31/2017

Comments:
Assessing Impact of IVIV Scaling Factor Variability in Pediatric Populations on Measures of Internal Exposure Using PBPK Modeling

☐ Superfund — Accounting and Appropriations Data — [X] Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (*Max 2*): ☐

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

Contract Period: 11/01/2013 To 10/31/2017 — Cost/Fee: — LOE:

This Action:

Total:

Work Plan / Cost Estimate Approvals

Contractor WP Dated: — Cost/Fee — LOE:

Cumulative Approved: — Cost/Fee — LOE:

Work Assignment Manager Name: Karen Herbin-Davis (Signature) (Date)	Branch/Mail Code: Phone Number: 919-541-0857 FAX Number:
Project Officer Name: Melissa Revely-Wilson (Signature) (Date)	Branch/Mail Code: Phone Number: 919-541-0207 FAX Number:
Other Agency Official Name: (Signature) (Date)	Branch/Mail Code: Phone Number: FAX Number:
Contracting Official Name: William Yates (Signature) (Date)	Branch/Mail Code: Phone Number: 513-487-2055 FAX Number:

PERFORMANCE WORK STATEMENT 3-83
Contract EP-C-14-001

TITLE: Assessing Impact of IVIV Scaling Factor Variability in Pediatric Populations on Measures of Internal Exposure Using PBPK Modeling

PERIOD OF PERFORMANCE:

CONTRACTING OFFICER REPRESENTATIVE (COR):

Karen Herbin-Davis
US EPA / NHEERL-RTP
B105-03, RTP, NC 27711
Phone: (919) 541-0857
Fax (919) 541-4284
Herbin-davis.karen@epa.gov

(Alt COR): Michael F. Hughes
US EPA / NHEERL-RTP
B105-03, RTP, NC 27711
Phone: (919) 541-2160
Fax (919) 541-4284
Hughes.michaelf@epa.gov

I. PURPOSE

This work assignment is a follow-on to work performed in the Year 2 Option Period under Work Assignment # 2-83. The work continues from Task 1 through Task 4 during this Year 3 Option Period under Work Assignment 3-83. This PWS describes Tasks 1-4. Tasks 1 from Option Year 2 has been partially completed. The purpose of this PWS is to assist EPA in evaluating the impact of in vitro to in vivo (IVIV) scaling factor variability in pediatric populations on measures of internal exposure using PBPK modeling. The estimated level of effort for this work is described in Tasks 1-4. In all areas of work, application of models, and methods development, the technical expert shall provide to the COR written technical direction for the contractor, as needed, to assist in the quality assurance of the modelling effort, and to ensure that the information resources are compatible with EPA's computer based information systems and specifications.

In order to improve EPA's ability to provide quality assurance (QA) and quality control (QC) for PBPK models, it is important that documentation of all QA processes and any changes in the model code or scripts be thorough and complete. Comments shall be added to model files and scripts as necessary and the full electronic record shall include the entire model workspace in Acslx, copies of Excel or other ancillary files which contain simulation data, and a summary word document which logs the QA activities, process, and results.

II. BACKGROUND

Many physiologically based pharmacokinetic (PBPK) models include values for metabolic rate parameters extrapolated from in vitro metabolism studies using scaling factors such as mg of microsomal protein per gram of liver (MPPGL) and liver mass (FVL). Variation in scaling factor values impacts metabolic rate parameter estimates (Vmax) and hence estimates of internal dose used in dose response analysis. The impacts of adult human variation in MPPGL and FVL on estimates of internal dose have previously been assessed using a human PBPK model for bromodichloromethane (BDCM) for multiple biomarkers of exposure and internal dose for a variety of household water use scenarios. The purpose of this work is to extend this analysis to pediatric populations.

III. STATEMENT OF WORK

A. Objective

The purpose of this PWS is to evaluate the impact of in vitro to in vivo (IVIV) scaling factor variability in pediatric populations on biomarkers of exposure and internal dose using PBPK modeling for some common household water use scenarios for the disinfection by-product, BDCM. This is an extension of work already conducted in adult humans using BDCM as a model chemical.

B. Tasks

Task 1: Work Plan - Review of Model Code and Scoping of Work

The contractor shall review all provided model code, associated scripts and other documentation pursuant to accomplishment of tasks 2-4 and shall provide an evaluation consisting of any technical clarifications necessary to complete the work, provisional schedule, level of effort and related documentation. The COR will provide the model code and related scripts, and various data needed to complete the analysis. Since the exact start dates are not yet known, the time to completion should be described as the number of days or weeks from the start of a particular task.

The contractor shall provide expertise in PBPK model analysis, evaluation, and development.

Task 2: Pediatric Model Parameterization and Testing

The COR shall provide from the technical expert source references for pediatric physiological parameters and raw data for scaling factors to be used, as well as example model scripts containing relevant parameters and test files. The contractor shall develop analogous pediatric scripts for model parameterization and testing and conduct such testing. Testing shall include evaluation of mass balance.

The contractor shall provide an interim report detailing any technical issues encountered during the course of Task 2.

Task 3: Monte Carlo and Exposure Scenario Analysis with Sensitivity Analysis
The COR will provide from the technical expert example scripts for exposure scenarios, Monte Carlo analyses, and local sensitivity analysis. The contractor shall develop analogous scripts to allow for Monte Carlo analysis according to provided household exposure scenarios and related sensitivity analysis for specified model parameters and model responses. The contractor shall perform Monte Carlo analysis for specific household exposure scenarios using specified model parameters and model responses.

The contractor shall provide an interim report detailing any technical issues encountered during the course of Task 3.

Task 4: Final Report
The contractor shall provide a final report that includes a summary of the work performed during the contract period, and may provide suggestions or comments for new initiatives, new resources, or future work to enhance assessment of the impact of IVIVE scaling factor variability in pediatric populations.

The final report shall include sections consistent with research reports including both methods, (e.g., parameter tables) and results (both tabular and graphical) as well as documentation of all QA processes and any changes in the model code or scripts. The full electronic record shall include the complete model workspace from acslx software, copies of Excel or other ancillary files which contain data generated in model simulations, a summary word document which logs the QA activities, process, and results. The report shall be provided in MS Word format, via email.

IV. SCHEDULE OF DELIVERABLES

Item / Task – Description	Estimated Deliverable Date
Task 1 - Review of Model Code and Scoping of Work	15 Calendar Days from Initiation of PWS
Task 2 - Pediatric Model Parameterization and Testing	25 Calendar Days from Initiation of PWS
Task 3 – Monte Carlo and Exposure Scenario Analysis with Sensitivity Analysis	45 Calendar Days from Initiation of PWS
Task 4 – Final Report	Three weeks prior to the completion of this PWS

V. MANAGEMENT CONTROLS

1. The contractor shall certify there is no conflict of interest. The contractor shall provide the following conflict of interest certification in the workplan:

> I certify that, to the best of my knowledge and belief, no actual, apparent, or potential organizational or individual conflicts of interest related to this Work Assignment exist. Personnel, who perform work under this Work Assignment, or relating to the Work Assignment, have been informed of their obligation to report personal and organizational interests. All actual, apparent or potential organizational or individual conflicts of interest related to this Work Assignment have been reported to the Contracting Officer (CO) and Project Officer (PO) or are attached, if applicable.

2. The contractor shall be responsible for obtaining a conflict of interest certification for any subcontractor services.

3. All deliverables shall be reviewed for conformance to the requirements of this PWS before being approved as final.

VII. NOTICE REGARDING GUIDANCE PROVIDED UNDER THIS WORK ASSIGNMENT

Guidance is strictly limited to technical and analytical support. The contractor shall not engage in activities of an inherent governmental nature such as the following:

(1) Formulation of Agency policy
(2) Selection of Agency priorities
(3) Development of Agency regulations

Should the contractor receive any instruction from an EPA staff person that the contractor ascertains to fall into any of these categories or goes beyond the scope of the contract or Work Assignment, the contractor shall immediately contact the COR.

The contractor shall also ensure that work under this PWS does not contain any apparent or real personal or organizational conflict of interest. The contractor shall certify that none exist at the time the proposal is submitted to EPA.

VIII. SPECIAL CONDITIONS AND ASSUMPTIONS

In addition to the standard reporting requirements of the contract, the contractor shall hold a conference call with the COR at the initiation of the PWS and shall subsequently discuss with the COR by telephone or e-mail, as needed, any technical issues that might impact the successful completion of the objectives of this PWS.

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 3-86

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-14-001	11/01/2013 To 10/31/2017	Dust & Soil Ingestion Study
	Base Option Period Number 3	

Contractor: ICF INCORPORATED, L.L.C.

Specify Section and paragraph of Contract SOW:

Purpose:
- [X] Work Assignment
- [ ] Work Assignment Amendment
- [ ] Work Plan Approval
- [ ] Work Assignment Close-Out
- [ ] Incremental Funding

Period of Performance: From 11/01/2016 To 10/31/2017

Comments:

WA 3-86, Study Design Support for a Dust & Soil Ingestion Study. SHC 2.63.8. This is a new work assignment (WA) and follow-on to 2-86. The effective date of the new WA shall be the date of issuance by the CO. The Contractor shall supply a WP/CE no later that 20 days from the effective date of the WA. WACOR: N. Tulve

☐ Superfund — Accounting and Appropriations Data — ☒ Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (*Max 2*): ☐

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

	Cost/Fee	LOE
Contract Period: 11/01/2013 To 10/31/2017		0
This Action:		1,628
Total:		1,628

Work Plan / Cost Estimate Approvals

	Cost/Fee	LOE
Contractor WP Dated:		
Cumulative Approved:		

Work Assignment Manager Name: Nicolle Tulve (Signature) (Date)	Branch/Mail Code: Phone Number: 919-541-1077 FAX Number:
Project Officer Name: Melissa Revely-Wilson (Signature) (Date)	Branch/Mail Code: Phone Number: 919-541-0207 FAX Number:
Other Agency Official Name: (Signature) (Date)	Branch/Mail Code: Phone Number: FAX Number:
Contracting Official Name: William Yates (Signature) (Date)	Branch/Mail Code: Phone Number: 513-487-2055 FAX Number:

PERFORMANCE WORK STATEMENT
CONTRACT NO. EP-C-14-001, OPTION 3
WA 3-86

TITLE: Study Design Support for a Dust and Soil Ingestion Study

Specify Section & Paragraph SOW: III.C.

PERIOD of PERFORMANCE: CO approval through 10/31/2017.

I. PURPOSE.

The purpose of this work assignment is for the U.S. Environmental Protection Agency's (EPA), Office of Research and Development (ORD), National Center for Environmental Assessment (NCEA) and National Exposure Research Laboratory (NERL) to obtain assistance for design elements to support a potential study to estimate dust and soil ingestion rates among various age groups of children (0-<1 month; 1-<3 months; 3-<6 months; 6-<12 months; 1-<2 years; 2-<3 years; 3-<6 years; 6-<11 years; 11-<16 years; 16-<21 years) and adults in the U.S.

II. BACKGROUND AND OBJECTIVES.

Dust and soil ingestion are important pathways of exposure to certain environmental contaminants, especially for children. Assessing exposure via these pathways requires information on dust and soil ingestion rates. There are three approaches for estimating dust and soil ingestion rates, as reported in the scientific literature: tracer studies, activity pattern studies, and biokinetic modeling comparison studies. Tracer studies estimate dust and soil ingestion based on measurements of tracer elements present in dust and soil from children's residences and/or play areas, and the children's feces. Activity pattern studies combine information on hand-to-mouth and object-to-mouth activities with assumptions about transfer of dust and soil to hands and from hands to mouth and other exposure factors (e.g., frequency of hand washing) to derive dust and soil ingestion estimates. Micro-activity information is usually obtained using observational techniques (e.g., videography, direct observation) or from survey responses (e.g., questionnaires). Biokinetic modeling comparison studies compare direct measurements of a biomarker (e.g., blood or urine levels of a toxicant) with predictions from a biokinetic model (e.g., IEUBK). The comparison of the model predicted blood lead levels with actual blood lead levels can be used to confirm the data inputs on dust and soil intake rates. The available dust and soil ingestion data based on these three study types are reviewed in detail in EPA's Exposure Factors Handbook: 2011 Edition[1], but the data are limited and ingestion rates are not available for all child-specific age ranges (0-<1 month; 1-<3 months; 3-<6 months; 6-<12 months; 1-<2 years; 2-<3 years; 3-<6 years; 6-<11 years; 11-<16 years; 16-<21 years). In addition, the contribution that dust makes to the total intake is not adequately characterized. Therefore, ORD is considering the collection of additional data to fill critical data gaps using the tracer and/or activity pattern approaches. The initial phase of this project consisted of a feasibility assessment for a dust and soil ingestion study prepared by EPA, which used information on potential sample sizes based on work conducted under WA 1-64. WA 2-86 used the sample size estimates from WA 1-64 to write a draft study design describing a study to collect data in order to estimate dust and soil ingestion rates for children and adults. WA 3-86 builds from the

1 EPA/600/R-09/052F; and Moya, J. and Phillips, L. (2014) A review of soil ingestion studies for children. J Expos Sci Env Epidem, 24: 545-554.

work in WAs 1-64 and 2-86 to expand specific design elements for a proposed dust and soil ingestion study. This PWS describes the tasks to be completed during this Year 3 Option Period for WA 3-86. Tasks 1-3 were completed under WA 2-86. Tasks 11-14 shall be completed prior to completing tasks 4-10.

III. STATEMENT OF WORK.

The contractor shall be responsible for completion of several tasks. A summary of each task is provided below, including the time frame during which the task shall be completed.

Task 1. The contractor shall establish initial communication, submit a work plan, and arrange for routine updates for the EPA Contracting Officer's Representative (COR).

The contractor shall schedule an initial conference call with the EPA COR **within 1 week** after receipt of the work assignment to discuss any questions that ICF may have before submitting the work plan.

Deliverable 1: The contractor shall arrange a conference call with the COR **within 1 week after receipt of the work assignment.**

Status of Task 1 and Deliverable 1: Completed.

Task 2. The contractor shall arrange a conference call to discuss the technical basis of this task with EPA.

EPA ORD has established a team of scientists to work on the development of a study design for a dust and soil ingestion study. The contractor shall organize a meeting between these EPA ORD scientists and the ICF contractor(s) working on this work assignment to discuss the scope of the project. The contractor(s) shall familiarize themselves with the final deliverables from work assignments 1-64 and 2-86 prior to the meeting. **Within 2 weeks after Work Plan approval,** the contractor shall arrange for a conference call with the EPA COR and the EPA ORD scientists working on the study design to discuss the scope of this work assignment.

Deliverable 2: The contractor shall arrange a conference call **within 2 weeks after Work Plan approval**.

Status of Task 2 and Deliverable 2: Completed.

Task 3. The contractor shall develop an outline for the dust and soil ingestion study design.

The contractor shall develop an outline for the study design document. The study design outline shall address design considerations for incorporating both the tracer and activity pattern methodologies. It shall include, but not be limited to, topics such as rationale and background, justification, objectives, strengths and limitations of the proposed study, sample size and representativeness, target population(s) and recruitment methods, study location(s), eligibility, recruitment, multimedia measurement plan, target analytes and justification for the selection of those analytes, data analysis plan, considerations for the protections of human subjects (included as an appendix), sample collection procedures, sample analysis, data security and confidentiality, statistical analysis of the data and data reporting methods, quality assurance, and references. It shall also address both pilot and full study implementation phases. Information from the statistical analysis that was conducted under

work assignment 1-64 of this contract to estimate the number of participants and the types and numbers of samples needed shall be incorporated into the study design, as appropriate. The contractor shall submit the draft outline for the study design **within 2 weeks after completing Task 2.** The contractor shall submit the final outline **within 2 weeks of receiving comments on the draft outline from the COR.**

Deliverable 3a: The contractor shall submit the draft outline **within 2 weeks after completing Task 2.**

Deliverable 3b: The contractor shall submit a final outline **within 2 weeks of receiving comments on the draft outline from the COR.**

Status of Task 3 and Deliverables 3a and 3b: Completed.

Task 4. The contractor shall develop the study design document.

The contractor shall develop a draft study design document based on the outline prepared in Task 3. The study design document shall include detailed descriptions of all design elements identified in the outline. The contractor shall provide the internal review draft study design document **within 8 weeks of completing Task 3.** An external review draft study design shall be submitted to the COR **within 4 weeks after receiving comments from the EPA COR on the internal review draft document.**

Deliverable 4a: The contractor shall submit to the COR the internal review draft study design **within 8 weeks after receiving EPA concurrence on Task 3.**

Deliverable 4c: The contractor shall submit to the COR the revised internal review draft study design document **within 8 weeks after receiving EPA concurrence on completing Tasks 11-14.**

Deliverable 4b: The contractor shall submit the external review draft study design document **within 4 weeks of receiving comments from the COR on deliverable 4c.**

Status of Task 4 and Deliverable 4a: In progress. Tasks 11-14 should be completed so that Task 4 can then be completed.

Task 11. Uncertainty and Variability Analyses

The contractor shall complete uncertainty and variability analyses for the sample size estimates in the draft study design that was completed as part of WA 2-86 (Task 4). These analyses will document the uncertainty and variability surrounding the sample size estimates calculated in WA 1-64 for each age group. These uncertainty and variability analyses will show the range of soil and dust ingestion values needed such that differences between the age groups can be measured. The contractor shall use the published data that was used for WA 1-64 and not attempt to obtain the raw data behind these publications.

Deliverable 11a: The contractor shall provide a table showing the sample size estimates and the associated uncertainty and variability **within 4 weeks of receiving this WA for Option Year 3**.

Task 12. Modeled Estimates of Dust and Soil Ingestion Rates for Children

The contractor shall use available data to calculate modeled estimates of dust and soil ingestion rates for all child-specific age ranges (0-<1 month; 1-<3 months; 3-<6 months; 6-<12 months; 1-<2 years; 2-<3 years; 3-<6 years; 6-<11 years; 11-<16 years; 16-<21 years) where data are available. The contractor shall provide all original data, supporting information, and references for data sources used. The contractor shall provide details on the modeling approach, data inputs, limitations, uncertainties, and assumptions used in making these estimates.

Deliverable 12a: The contractor shall provide a draft letter report detailing the methods and approaches used and the modeled estimates of dust and soil ingestion rates for children **within 8 weeks of completing Task 11.**

Deliverable 12b: The contractor shall provide a final letter report detailing the methods and approaches used and the modeled estimates of dust and soil ingestion rates for children **within 4 weeks of receiving the comments from the EPA COR on deliverable 12a.**

Task 13. Modeled Estimates of Dust and Soil Ingestion Rates for Adults

The contractor shall use available data to calculate modeled estimates of dust and soil ingestion rates for adults >21 years of age. The contractor shall provide all original data, supporting information, and references for data sources used. The contractor shall provide details on the modeling approach, data inputs, limitations, uncertainties, and assumptions used in making these estimates.

Deliverable 13a: The contractor shall provide a draft letter report detailing the methods and approaches used and the modeled estimates of dust and soil ingestion rates for adults **within 4 weeks of completing Task 12.**

Deliverable 13b: The contractor shall provide a final letter report detailing the methods and approaches used and the modeled estimates of dust and soil ingestion rates for adults **within 4 weeks of receiving the comments from the EPA COR on deliverable 13a.**

Task 14. Literature Review of Potential Candidate Compounds

The contractor shall complete a literature review to determine if there are potential candidate compounds that can be used for a dust and soil ingestion study. These compounds should be ubiquitous and unique to dust. A different compound(s) should be ubiquitous and unique to soil. These compounds should not be the elemental tracers that have been historically used as tracers. The contractor shall document why these candidate compounds would be good tracers for a field study estimating soil and dust ingestion rates.

Deliverable 14a: The contractor shall provide a draft letter report detailing the methods and approaches used to identify potential candidate compounds **within 8 weeks of completing Task 13.**

Deliverable 14b: The contractor shall provide a final letter report **within 4 weeks of receiving comments from the EPA COR on deliverable 14a.**

Task 5. The contractor shall develop a Quality Assurance Project Plan for the implementation of the study design.

The contractor shall develop a Quality Assurance Project Plan (QAPP) that documents the quality processes and procedures for implementing the study design developed under Task 4. The contractor shall submit the QAPP for the EPA COR's and QA Manager's approval. The QAPP shall include documentation on quality assurance checks to verify accuracy, completeness, and adherence to established standards and format, and must address data collection and analysis. Guidance for developing EPA G-5 compliant QAPPs that meet EPA specifications prepared for activities conducted by or funded by EPA, are available online at http://www.epa.gov/quality/qa_docs.html, see "EPA Requirements for Quality Assurance Project Plans (QA/R-5)". The contractor shall provide the COR with the draft QAPP **within 4 weeks of completing Task 7.** The final QAPP shall be submitted to the COR **within 2 weeks of receiving comments on the draft QAPP from the EPA COR and QA Manager.**

Deliverable 5a: The contractor shall provide the COR with the draft QAPP **within 4 weeks of completing Task 4.**

Deliverable 5b: The contractor shall provide the COR with the final QAPP **within 2 weeks of receiving comments from the EPA COR and QA manager.**

Task 6. The contractor shall develop standard operating procedures (SOPs) for the implementation of the study design.

The contractor shall develop SOPs for any multimedia sample that will be collected in the field based on the study design and QAPP requirements developed under Tasks 4 and 5. The SOPs shall include, but not be limited to, scope and application, summary of method, definitions, cautions, responsibilities, materials and reagents, procedures, records, quality control and quality assurance, references, and chain of custody record. The SOPs shall be drafted in an approved ORD format and submitted with the draft and final QAPP. It is acceptable for existing SOPs to be adapted for this work, as appropriate. EPA will provide an SOP in an approved format to the contractor to be used as an example.

Deliverable 6a: The contractor shall provide the COR with the draft SOPs at the same time as the draft QAPP.

Deliverable 6b: The contractor shall provide the COR with the final SOPs at the same time as the final QAPP.

Task 7. Implementation Plan for the study design.

The contractor shall develop a draft implementation plan to accompany the study design document. The draft implementation plan will contain sufficient detail to ensure successful execution of the study design. The elements found in the draft implementation plan will match the elements found in the final study design. If appropriate, the implementation plan details may be incorporated into the study design, so that only one document is submitted.

Deliverable 7a: The contractor shall provide the COR with a draft implementation plan **within 4 weeks of completing Task 4.**

Deliverable 7b: The contractor shall provide the COR with a final implementation plan **within 2 weeks of receiving comments from the EPA COR on deliverable 7a.**

Task 8. Recruitment materials.

The contractor shall develop draft recruitment materials based on the recruitment strategy included in the study design. The draft recruitment materials may include, but are not limited to, flyer advertisements, public service announcements, and other materials that would interest potential participants in participating in the study.

Deliverable 8a: The contractor shall provide the COR with draft recruitment materials **within 4 weeks of completing Task 7.**

Deliverable 8b: The contractor shall provide the COR with final recruitment materials **within 2 weeks of receiving comments from the EPA COR on deliverable 8a.**

Task 9. Questionnaire

The contractor shall develop a draft questionnaire to be used in the potential study. The questions in the questionnaire will be included because they support the multimedia samples being collected. The questionnaire will be used to collect demographic information and data needed to allocate participants' time between indoor and outdoor locations. Additional topics to be included in the questionnaire are those pertaining to the likelihood of dust and soil intake (e.g., hand washing frequency, thumb-sucking, and behaviors that might indicate pica). The contractor shall review available questionnaires that have been used in previous dust and soil ingestion studies, as needed, to identify other relevant topics and questions that should be included. EPA will provide examples of questionnaires and a list of important aspects for consideration. In addition to the draft questionnaire, the contractor shall develop a summary document that explains the justification, source, and previous use of the question, if applicable.

Deliverable 9a: The contractor shall provide the COR with a draft questionnaire **within 4 weeks of completing Task 8.**

Deliverable 9b: The contractor shall provide the COR with a final questionnaire **within 2 weeks of receiving comments from the EPA COR on deliverable 9a.**

Task 10. Final Study Design

The peer review of the external review draft submitted under Task 7 will be conducted by EPA under a separate contract with an independent panel of experts. Once the external peer review is conducted and comments are received, the contractor shall review the external peer review comments within 2 weeks of receipt and arrange a

conference call with the EPA COR to discuss the comments and answer questions. The contractor shall incorporate external peer review comments into the study design and produce a 1) final study design and 2) response to comments document for EPA clearance within 6 weeks after the conference call with the EPA COR. In consultation with the EPA COR, more time may be allowed if comments are more significant than originally expected. The response to comments document shall summarize how external peer review comments were addressed in the final study design. The contractor shall address any comments resulting from the EPA clearance process within 1 week of receipt of those comments.

Deliverable 10a: Arrange for conference call with EPA COR **within 1 week of receipt of external peer review comments**.

Deliverable 10b: Produce a final study design and response to comments document **within 6 weeks of completing the conference call with the EPA COR**.

The contractor shall furnish electronic copies of (or internet links to) any references or other materials obtained in the preparation of the deliverables for this work assignment.

IV. TIME TABLE.

Task	Deliverable	Time frame	Status
1	Establish initial communication	Within 1 week after receipt of work assignment	Completed
2	Hold conference call with EPA staff and contractor	Within 2 weeks of Work Plan approval	Completed
3a	Submit draft outline	Within 2 weeks of completing Task 2	Completed
3b	Submit final outline	Within 2 weeks of receiving comments from COR	
4a	Submit draft study design document	Within 8 weeks of COR concurrence on Task 3	In progress
4b	Submit final study design document	Within 4 weeks of COR comments	
11a	Submit uncertainty and variability analyses	Within 4 weeks of receiving WA for Option Year 3	
12a	Submit draft letter report on modeled ingestion estimates for children	Within 8 weeks of completing Task 11	
12b	Submit final letter report on modeled ingestion estimates for children	Within 4 weeks of receiving comments on Task 12a	
13a	Submit draft letter report on modeled ingestion estimates for adults	Within 4 weeks of completing Task 12	
13b	Submit final letter report on modeled ingestion estimates for adults	Within 4 weeks of receiving comments on Task 13a	
14a	Submit draft letter report on literature review	Within 8 weeks of completing Task 13	

14b	Submit final letter report on literature review	Within 4 weeks of receiving comments on Task 14a	
5a	Submit draft QAPP	Within 4 weeks of completing Task 4	
5b	Submit final QAPP	Within 2 weeks of COR and QA manager comments	
6a	Submit draft SOPs	At the same time as the draft QAPP	
6b	Submit final SOPs	At the same time as the final QAPP	
7a	Submit draft implementation plan	Within 4 weeks of completing Task 4	
7b	Submit final implementation plan	Within 2 weeks of receiving comments on Task 7a	
8a	Submit draft recruitment materials	Within 4 weeks of completing Task 7	
8b	Submit final recruitment materials	Within 2 weeks of completing Task 8a	
9a	Submit draft questionnaire	Within 4 weeks of completing Task 8	
9b	Submit final questionnaire	Within 2 weeks of completing Task 9a	
10a	Hold conference call	Within 1 week of external peer review comments	
10b	Submit final study design and response to comments document	Within 6 weeks of completing Task 10a	

1. The contractor shall be responsible for obtaining a conflict of interest certification for any subcontractor services.

2. All deliverables shall be in conformance with the requirements of the work assignment before such deliverables are approved as final. Electronic copy of all deliverable shall be sent to the EPA Project Officer (PO).

3. The contractor shall comply with other applicable requirements for final work assignment reports as stipulated in the Contractual Agreement.

4. The contractor shall prepare all deliverables in accordance with the Quality Management Plan for the contract.

V. NOTICE REGARDING GUIDANCE PROVIDED UNDER THIS TASK ORDER.

Guidance is strictly limited to technical and analytical support. The contractor shall not engage in activities of an inherent governmental nature such as the following:

(1) Formulation of Agency policy
(2) Selection of Agency priorities
(3) Development of Agency regulations

If the contractor receives any instructions from an EPA staff person that the contractor ascertains to fall into any of these categories or goes beyond the scope of the contract or work assignment, the contractor shall immediately notify the COR. The contractor shall also ensure that work under this Work Assignment does not contain any apparent or real personal or organizational conflict of interest. The contractor shall certify that no conflicts exist at the time the proposal is submitted to the EPA.

VII. EPA CONTACT INFORMATION.

Copies of all correspondence pertaining to the performance of this work assignment shall be sent electronically to the COR.

Work Assignment Manager	**Alternate WAM**
NICOLLE TULVE US EPA OFFICE OF RESEARCH AND DEVELOPMENT NATIONAL EXPOSURE RESEARCH LABORATORY 109 TW ALEXANDER DR. MD-E-205-04 RESEARCH TRIANGLE PARK, NC 27711 (919)541-1077 (919)541-0905 FAX TULVE.NICOLLE@EPA.GOV	LINDA PHILLIPS US EPA OFFICE OF RESEARCH AND DEVELOPMENT NATIONAL CENTER FOR ENVIRONMENTAL ASSESSMENT 1200 PENNSYLVANIA AVE. NW MC-8623P WASHINGTON DC 20460 (703)347-0366 (703)347-8690 FAX PHILLIPS.LINDA@EPA.GOV

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 3-88

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-14-001	11/01/2013 To 10/31/2017 Base Option Period Number 3	Multipollutant NAAQS

Contractor: ICF INCORPORATED, L.L.C.

Specify Section and paragraph of Contract SOW: D. Analysis, Document and Issue Paper Preparation

Purpose:
- [X] Work Assignment
- [ ] Work Assignment Amendment
- [ ] Work Plan Approval
- [ ] Work Assignment Close-Out
- [ ] Incremental Funding

Period of Performance: From 11/01/2016 To 10/31/2017

Comments:

☐ Superfund — Accounting and Appropriations Data — [X] Non-Superfund

SFO (*Max 2*): ☐

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
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Authorized Work Assignment Ceiling

Contract Period: 11/01/2013 To 10/31/2017 — Cost/Fee: — LOE:

This Action:

Total:

Work Plan / Cost Estimate Approvals

Contractor WP Dated: — Cost/Fee — LOE:

Cumulative Approved: — Cost/Fee — LOE:

Work Assignment Manager Name: Nicole Hagan (Signature) (Date)	Branch/Mail Code: Phone Number: 919-541-3153 FAX Number:
Project Officer Name: Melissa Revely-Wilson (Signature) (Date)	Branch/Mail Code: Phone Number: 919-541-0207 FAX Number:
Other Agency Official Name: (Signature) (Date)	Branch/Mail Code: Phone Number: FAX Number:
Contracting Official Name: William Yates (Signature) (Date)	Branch/Mail Code: Phone Number: 513-487-2055 FAX Number:

I. TITLE: Multipollutant Evidence for the National Ambient Air Quality Standards

II. WORK ASSIGNMENT CONTRACT OFFICER REPRESENTATIVES (WA COR):

Work Assignment Manager (WAM):
Nicole Hagan (mail code C504-06)
Ambient Standards Group
Health and Environmental Impacts Division
U.S. EPA, OAQPS
Research Triangle Park, NC 27711
Telephone: (919) 541-3153

Alternate Work Assignment Manager:
Breanna Alman (mail code C539-02)
Ambient Standards Group
Health and Environmental Impacts Division
U.S. EPA, OAQPS
Research Triangle Park, NC 27711
Telephone: (919) 541-2351

III. LEVEL OF EFFORT

Duration: 3 months
Completion Date: February 28, 2017

IV. BACKGROUND

Sections 108 and 109 of the Clean Air Act require periodic review and, if appropriate, revisions of the national ambient air quality standards (NAAQS) and the air quality criteria on which they are based. The purpose of this work assignment is to identify, recruit and manage qualified scientists to review, evaluate and compile currently available scientific information to inform our understanding of multipollutant health impacts, including impacts in at-risk groups. This information will be considered within the context of the NAAQS reviews, informing both our understanding of the potential policy implications of multipollutant exposures and our quantitative analyses of risks and exposures. This work assignment shall be conducted for the U.S. Environmental Protection Agency (hereinafter the EPA or Agency) Health and Environmental Impacts Division (HEID) and is consistent with the purpose and scope of Contract EP-C-14-001. NOTE: This work assignment is a follow-on to work performed in the Year 2 Option Period under Work Assignment #2-88. The work continues from Task 2c through Task 2d during this Year 3 Option Period under Work Assignment #3-88. Tasks 1, 2a, and 2b from Option Year 2 have been completed.

V. STATEMENT OF WORK

The WAM is authorized to provide technical direction to the Contractor in accordance with the terms of the contract. The Contractor shall not duplicate any work previously performed under WA 2-88. The Contractor shall perform the following tasks:

Task 1: Work Plan and Communications
The Contractor shall develop a work plan proposing a technical approach to address the Tasks within this WA. The Contractor shall provide the work plan to the WAM for review and approval prior to work. The Contractor shall provide monthly progress reports to the WAM after approval of the work plan to review progress of this WA. The Contractor shall maintain communication with the WAM through weekly phone calls and/or email updates.

Task 2: Screen and Extract Multipollutant Epidemiological Studies
Continuing the work from WA 2-88, for each health endpoint, the Contractor and/or expert scientists shall perform an initial screen of the EndNote libraries from task 2b of WA 2-88 to identify the studies that are multipollutant studies (e.g., using a title screen). The purpose of this is to remove any studies that are, based on the Contractor and/or expert scientists' judgment, not health-based multipollutant epidemiological studies. The Contractor and/or expert scientists shall categorize studies for each health endpoint as "yes" (i.e., studies that do evaluate the potential for health effects due to multipollutant exposures), "maybe" (i.e., studies that may evaluate the potential for health effects due to multipollutant exposures, but for which a definitive answer is not possible based on a title screen), or "no" (i.e., studies that do not evaluate the potential for health effects due to multipollutant exposures). For each health endpoint, the Contractor and/or expert scientists shall further evaluate the studies (e.g., through review of the abstract and methods) identified as "yes" and "maybe" in order to definitively identify epidemiological studies that include multipollutant analyses (e.g., joint pollutant; analyses of effect modification). Continuing the work from WA 2-88, the Contractor and/or expert scientists shall extract and tabulate study-specific information for the studies resulting from the screening process for each health endpoint. Tabulated information shall include, at a minimum, the study citation, the HERO identification number, the location of the study, the years of the study, the pollutants included in the study, and the health endpoint(s) considered. The Contractor shall work with the WAM to identify the information to be included in study tables, and to develop study tables, prior to beginning extraction of study information. The Contractor and/or expert scientists shall provide the epidemiological study table to the WAM upon completion of this subtask.

VI. DELIVERABLES:

Task	Deliverable	Due Date
1	**Work Plan and Communications**	
	Work plan	Within 21 days of effective date of WA
2	**Screen and Extract Multipollutant Epidemiological Studies**	

	Extraction tables for epidemiological determined to be multipollutant studies	February 17, 2017

VII. REPORTING REQUIREMENTS

All reports shall be submitted in accordance with the contract specifications. In addition, the Contractor shall prepare all deliverable reports in Microsoft Word 2013. Any spreadsheet deliverables shall be delivered in Microsoft Excel 2013. The Contract shall submit an electronic copy of all deliverables to the WAM by email. The contractor shall ensure that all deliverables are free from computer viruses and spyware.

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 3-88

☐ Other ☒ Amendment Number: 000001

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-14-001	11/01/2013 To 10/31/2017 Base Option Period Number 3	Multipollutant for the NAAQS

Contractor: ICF INCORPORATED, L.L.C.

Specify Section and paragraph of Contract SOW:

Purpose:
- ☐ Work Assignment
- ☒ Work Assignment Amendment
- ☐ Work Plan Approval
- ☐ Work Assignment Close-Out
- ☐ Incremental Funding

Period of Performance: From 11/01/2016 To 10/31/2017

Comments: Revised PWS and add Alt. COR

☐ Superfund — Accounting and Appropriations Data — ☒ Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (*Max 2*): ☐

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
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Authorized Work Assignment Ceiling

Contract Period: 11/01/2013 To 10/31/2017 — Cost/Fee: — LOE:

This Action:

Total:

Work Plan / Cost Estimate Approvals

Contractor WP Dated: — Cost/Fee — LOE:

Cumulative Approved: — Cost/Fee — LOE:

Work Assignment Manager Name: Nicole Hagan (Signature) (Date)	Branch/Mail Code:	
	Phone Number: 919-541-3153	
	FAX Number:	
Project Officer Name: Melissa Revely-Wilson (Signature) (Date)	Branch/Mail Code:	
	Phone Number: 919-541-0207	
	FAX Number:	
Other Agency Official Name (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	
	FAX Number:	
Contracting Official Name: William Yates (Signature) (Date)	Branch/Mail Code:	
	Phone Number: 513-487-2055	
	FAX Number:	

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 3-90

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-14-001	11/01/2013 To 10/31/2017 Base Option Period Number 3	Technical and Administrative s

Contractor: ICF INCORPORATED, L.L.C.

Specify Section and paragraph of Contract SOW: A.1A (bullet 7) and C.1

Purpose:
- [X] Work Assignment
- [ ] Work Assignment Amendment
- [ ] Work Plan Approval
- [ ] Work Assignment Close-Out
- [ ] Incremental Funding

Period of Performance: From 11/01/2016 To 10/31/2017

Comments:

☐ Superfund — Accounting and Appropriations Data — [X] Non-Superfund

SFO (*Max 2*): ☐

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
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3										
4										
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Authorized Work Assignment Ceiling

	Cost/Fee	LOE
Contract Period: 11/01/2013 To 10/31/2017		
This Action:		
Total:		

Work Plan / Cost Estimate Approvals

	Cost/Fee	LOE
Contractor WP Dated:		
Cumulative Approved:		

Work Assignment Manager Name: Vicki Soto (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	703-347-0290
	FAX Number:	
Project Officer Name: Melissa Revely-Wilson (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	919-541-0207
	FAX Number:	
Other Agency Official Name (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	
	FAX Number:	
Contracting Official Name: William Yates (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	513-487-2055
	FAX Number:	

PERFORMANCE WORK STATEMENT
CONTRACT NO. EP-C-14-001
WA 3-90

TITLE: Technical and Administrative support for Assessment Coordination and Development in NCEA

Specify Section & Paragraph SOW: A.1A (bullet 7) and C.1

PERIOD of PERFORMANCE: Contract Award thru - October 31, 2017

I. PURPOSE

The purpose of this continuing work assignment is to provide services to the U.S. Environmental Protection Agency's (hereinafter EPA or Agency) National Center for Environmental Assessment (NCEA) IRIS Program to support both current program management as well as individual project management activities related to assessment development and production practices. This will address cross-cutting assessment and organizational issues that impact the development of IRIS assessments. Results will include further implementation of improved process methods and/or tools designed to track and facilitate an increase in the pace of development of multiple ongoing assessments within NCEA that were identified in WA 2-90.

II. BACKGROUND

The National Center for Environmental Assessment (NCEA), a major component of EPA's Office of Research and Development (ORD), with headquarters in Washington, DC, is EPA's national resource center for human health and ecological risk assessment. NCEA occupies a critical position in ORD between researchers in other parts of ORD and outside of EPA who are generating new findings and data, and the regulators in EPA's program offices and regions who must make regulatory, enforcement, and remedial action decisions. NCEA prepares technical reports and assessments that integrate and evaluate the most up-to-date research and serve as major elements of the science foundation supporting EPA policies. As a result, NCEA plays an important role as a consultant to EPA programs and regions on the use of science in environmental decision making and also influences the direction of environmental research.

III. STATEMENT OF WORK

This work assignment will provide technical and administrative support to NCEA to facilitate tracking, management and production of multiple ongoing assessments within the IRIS Program.

Task 1: Establish Communication

Within 3 days of the start date of this WA, the Contractor shall schedule a conference call (not to exceed 1 hour) with the WAM and other EPA staff and any appropriate contractor staff to clarify outstanding questions and confirm the schedule of specific tasks. Copies of all correspondence pertaining to the performance of this work assignment shall be sent to the Project Officer.

Task 2: Work Plan and Staffing Plan

The Contractor shall prepare a Technical Work Plan describing how the work outlined in this Performance Work Statement will be performed, including deliverables, a schedule, budget, and level of effort. The Contractor shall also prepare a Staffing Plan, which shall be submitted as part of the Work Plan that shows assigned personnel by task and the qualifications of the proposed personnel.

Deliverables: Technical Work Plan and Staffing Plan

Task 3: Further Implementation of Methods to Improve Assessment Activities at the Project Level

Consistent with the written assessment developed in WA 2-90 or further identified improvements, proposed changes to practices, modification and/or development of tools, and implementation plans selected by NCEA will be initiated. The contractor will do the following:

- Provide further recommendations for staged implementation of new and/or modified methods or approaches for continued improvement in assessment coordination and development activities. Work towards involving all active or new assessments in developing improved project management.
- Develop or provide tools that will assist in implementation of project management activities and provide training to support implementation of these tools.
- Recommend reporting or tracking processes, and provide training to support implementation of new processes.
- Identify, track, and analyze metrics to measure progress towards goals, as changes are implemented at the project level.
- Work directly with assessment team staff to develop and maintain assessment tracking and reporting measures. Assist with facilitating meetings and schedules.

Deliverables: Summaries of progress, meeting minutes, decision documentation, assessment tracking documentation.

Task 4: Further Implementation of Methods to Improve Assessment Activities at the Program Level

Consistent with the written assessment developed in WA 2-90 or further identified improvements, proposed changes to practices, modification and/or development of tools, and implementation plans selected by NCEA will be initiated. The contractor will do the following:

- Provide further recommendations for staged implementation of new and/or modified methods or approaches for continued improvement in program activities.
- Develop or provide tools that will assist in implementation of program management activities, and provide training to support implementation of these tools.
- Recommend reporting or tracking processes, and provide training to support implementation of new processes.
- Based on recommendations selected by NCEA, identify, track, and analyze metrics to measure progress towards goals, as changes are implemented in the IRIS Program.
- Work directly with program staff to develop and maintain assessment tracking and reporting measures at the program level. Assist with facilitating meetings and schedules.
- Continue to provide expert evaluation of project management software or other tools.
- Provide weekly briefings to NCEA/IRIS management on implementing program/project management activities. Document implementation with short summaries of progress and challenges.
- Meet with WAM and NCEA management weekly to discuss report of progress and challenges. Document meeting minutes including any decision points or resolutions.

Deliverables: Summaries of progress, meeting minutes, decision documentation.

Task 5: Assist in Implementing Project/Program Management System

Assist in standing up new project/program management system to be used at both the assessment level and the program level. Provide training and support to staff in use. Assist in developing functionality for use by staff and management. Assist in developing reports

Deliverables: Project/program management system.

In order to accomplish the majority of the activities of this Task, the Contractor(s) should participate in-person in the Potomac Yards NCEA offices.

IV. ANTICIPATED DELIVERABLES

All products by the Contractor must be of high quality, written in a clear concise style, with a logical organization and presentation. Deliverables shall be provided to EPA in electronic formats compatible with EPA-supported software (e.g., Excel spreadsheets, Word documents, PDFs, InDesign).

V. DELIVERABLES AND SCHEDULE

Task 1: Establish communication	3 days after award of WA and to schedule set
Task 2: Work plan/Staffing plan	15 days after award
Task 3: Implementation and management tools project level	Reports weekly
Task 4: Implementation and management tools program level	Reports weekly
Task 5: Project management software (if needed)	Reports weekly

VI. MANAGEMENT CONTROLS

1. All deliverables shall be reviewed for conformance to the requirements of this work assignment before being approved as final.

2. The contractor shall comply with other applicable requirements for final work assignment reports stipulated in contract.

VII. NOTICE REGARDING GUIDANCE PROVIDED UNDER THIS PROJECT

Guidance is strictly limited to technical and analytical support. The contractor shall not engage in activities of an inherent governmental nature such as the following:

(1) Formulation of Agency policy
(2) Selection of Agency priorities
(3) Development of Agency regulations

Should the contractor receive any instruction from an EPA staff person that the contractor ascertains to fall into any of these categories or goes beyond the scope of the contract or work assignment, the contractor shall immediately contact the PO, WAM, or CO.

The contractor shall also ensure that work under this work assignment does not contain any apparent or real personal or organizational conflict of interest. The contractor shall certify that none exist at the time the proposal is submitted to EPA.

VIII. SPECIAL CONDITIONS AND ASSUMPTIONS

The contractor shall hold a conference call with the WAM at the initiation of the work assignment. Standard reporting requirements of the contract apply for active/completed projects.

IX. OTHER REQUIREMENTS

The WAM will have oversight on all materials developed by the contractor. The primary communication mechanism between the WAM and the contractor shall be email.

In cases where the work to be performed is of a highly scientific or technical nature or requires consultation or interactions, it may be more expedient for the contractor to interact directly with members of the scientific/technical staff.

X. EPA CONTACT INFORMATION

Copies of all correspondence pertaining to the performance of this WA shall be sent to the PO.

Work Assignment Manager:

Vicki Soto
U.S. EPA/ORD/NCEA
MC 8601-P
1200 Pennsylvania Ave. NW
Washington, DC 20460
soto.vicki@epa.gov
(703) 347-0290

Alternate Work Assignment Manager:

James Avery
U.S. EPA/ORD/NCEA
MC 8601-P
1200 Pennsylvania Ave. NW
Washington, DC 20460
avery.james@epa.gov
(703) 347-8668